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CASE REPORT FORMS

Site no.	☐☐	Subject No.	☐☐☐
		Patient Initials	☐☐☐

CRF INDEX GUIDE (for printing)

EVRA

Patient/subject Screening Log

Sponsor:	ISRCTN Number:	Principal Investigator name:	Site Number:
Imperial College London	ISRCTN02335796		

Age	Date Screened	Sex (M/F)	ABPI	Superficial venous disease on colour duplex assessment deemed to be significant enough to warrant ablation by the treating clinician (either primary or recurrent venous reflux)? (Yes /No)	When did ulcer first appear? (dd/mm/yy)	Randomised (Yes/No)	Patient ID (if randomised)	Reason for Non-inclusion (if applicable) Age; ABPI (≥ 0.8 to be eligible); Superficial venous disease; Current leg ulceration of greater than 6 weeks, but less than 6 months duration; Other exclusion criteria (pls specify); Refused consent; Clinician decision (pls specify)

Please send screening logs to the Trial Manager regularly:
Email: evratrial@imperial.ac.uk
Fax: 0203 311 7362

Patient Initials____-_____- ___ Patient Date of birth _____/_____/_____

Inclusion / Exclusion Checklist

Inclusion Criteria

The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):		Yes	No
1.	Current leg ulceration of greater than 6 weeks, but less than 6 months duration	☐	☐
2.	Patient age ≥ 18 years	☐	☐
3.	Ankle Brachial Pressure Index (ABPI) ≥ 0.8	☐	☐
4.	Superficial venous disease on colour duplex assessment deemed to be significant enough to warrant ablation by the treating clinician (either primary or recurrent venous reflux)	☐	☐
5.	Able to give informed consent to participate in the study after reading the patient information	☐	☐
If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study.			

Exclusion Criteria

The following criteria MUST be answered NO for the participant to be included in the trial:		Yes	No
1.	Is there a presence of deep venous occlusive disease or other conditions precluding superficial venous intervention	☐	☐
2.	Is the patient unable to tolerate multilayer compression bandaging	☐	☐
3.	Inability of the patient to receive prompt endovenous intervention by recruiting centre	☐	☐
4.	Is the patient pregnant ☐ N/A - Male	☐	☐
5.	Is the leg ulcer of non-venous aetiology (as assessed by responsible clinician)	☐	☐
6.	Is the patient is deemed to require skin grafting	☐	☐
If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study.			

Signed_____ Dated _____

PATIENT CONSENT

Participant Informed Consent:	
Date participant signed written consent form:	__ __ / __ __ __ / __ __ __ __ (DD / MMM / YYYY)
Name of person taking informed consent: _____	

BASELINE VISIT **DEMOGRAPHIC DATA**

Date of Assessment: __ __ / __ __ __ / __ __ __ __

(DD / MMM / YYYY)

Demographic Data:				
Date of Birth:	__ __ / __ __ __ / __ __ __ __ (DD / MMM / YYYY)			
Sex: ☐ **Male** ☐ **Female**				
Ethnicity:				
White	White British ☐	White Irish ☐	White Other ☐	
Mixed race	White & Black Caribbean ☐	White & Black African ☐	White & Asian ☐	Other mixed background ☐
Asian or Asian British	Indian ☐	Pakistani ☐	Bangladeshi ☐	Other Asian background ☐
Black or Black British	Caribbean ☐	African ☐	Black Other ☐	
Chinese or other ethnicity	Chinese ☐	Other ☐ **(**please specify**)**		
Work: Is the patient retired? ☐ Yes ☐ No If No: **Worker** ☐ **employee** ☐ **self-employed** ☐ **and contractor** ☐ **director** ☐ **office holder** ☐ **Occupation**_____				

PREGNANCY (IF FEMALE)

☐ Male = Not Applicable	
☐ Female Date of Test	__ __ / __ __ __ / __ __ __ __ **(DD / MMM / YYYY)**
Result	☐ **Negative** ☐ **Positive = DO NOT RANDOMISE**

GIVE PATIENT QUESTIONAIRES (BEFORE PT TOLD OF TREATMENT ALLOCATION)

1) SF-36
2) AVVQ
3) EQ-5D

RANDOMISATION/ENROLMENT (SEE HANDBOOK FOR INSTRUCTIONS ON HOW TO RANDOMISE)

Participant Randomisation/Enrolment	
Participant study Number allocated:	____ ____ ____
Treatment Arm	☐ **Early** ☐ **Delayed**

VISIT 1 BASELINE **VITAL SIGNS**

Height:	___ ___ ___ . ___ cm	**Weight:**	___ ___ ___ . ___ kg

VISIT 1 BASELINE **SMOKING STATUS**

Has the participant ever smoked? ☐ **Never** ☐ **Yes,** Complete below

☐ **Current Smoker**

Smoked for ___ ___ years

Participant's average daily use:
- Number of cigarettes per day : ___ ___

☐ **Former smoker**

Date when smoking started: __ __ __ / __ __ __ __
MMM / YYYY

Date when smoking ceased: __ __ __ / __ __ __ __
MMM / YYYY

When smoking, participant's average daily use:
- Number of cigarettes per day : ___ ___

Comments:

VISIT 1 (BASELINE) **MEDICAL HISTORY**

☐ N/A - Male **If female: Previous Pregnancies** **If yes History of DVT in pregnancy**	☐ Yes ☐ No ☐ Yes ☐ No
☐ N/A - Male **If female: Current or history of hormone therapy**	☐ **None** ☐ **Previous HRT** ☐ **Current HRT** ☐ **Previous oral Contraceptives** ☐ **Current oral contraceptives**
History of Rheumatoid disease	☐ Yes ☐ No
Previous history of DVT	☐ Yes ☐ No
Currently taking Antiplatelet therapy	☐ **None** ☐ **Aspirin** ☐ **Clopidogrel** ☐ **Other:** _____
Currently taking Anticoagulation therapy	☐ **None** ☐ **Warfarin** ☐ **New Oral Anticoagulants:** _____ ☐ **Other:** _____
Currently taking Steroids	☐ Yes ☐ No
Currently taking Trental (pentoxyfilne)	☐ Yes ☐ No
Diabetic	☐ Yes Type 1 ☐ Type 2 ☐ ☐ No

VISIT 1 (BASELINE) **ULCER HISTORY**

Previous leg ulcer	☐ Yes: Date / __ __ __ / __ __ __ __ (MMM / YYYY) ☐ Right ☐ Left ☐ Both ☐ No
Previous leg ulcer treatment:	☐ Compression bandaging ☐ Liquid sclerotherapy ☐ Foam sclerotherapy ☐ GSV surgery ☐ SSV surgery ☐ Laser ablation ☐ Radiofrequency ablation ☐ Phlebectomy ☐ Other: _____

VISIT 1 (BASELINE) **CURRENT ULCER**

Date Appeared	Date / __ __ __ / __ __ __ __ (MMM / YYYY)
Trial Leg ulcer leg	☐ Right ☐ Left
Location	☐ Lateral ☐ Medial ☐ Circumferential
Size (from tracing – see Handbook for tracing instructions)	_____ cm2 Scan tracing as save as: PtTrialnumber_Baseline_tracing_dd/mm/yy Email to EVRAtrial@imperial.ac.uk
Take Photo (– see Handbook for photo instructions)	Save as: PtTrialnumber_Baseline_Photo_dd/mm/yy Email to EVRAtrial@imperial.ac.uk

VISIT 1 (BASELINE) **CURRENT COMPRESSION**

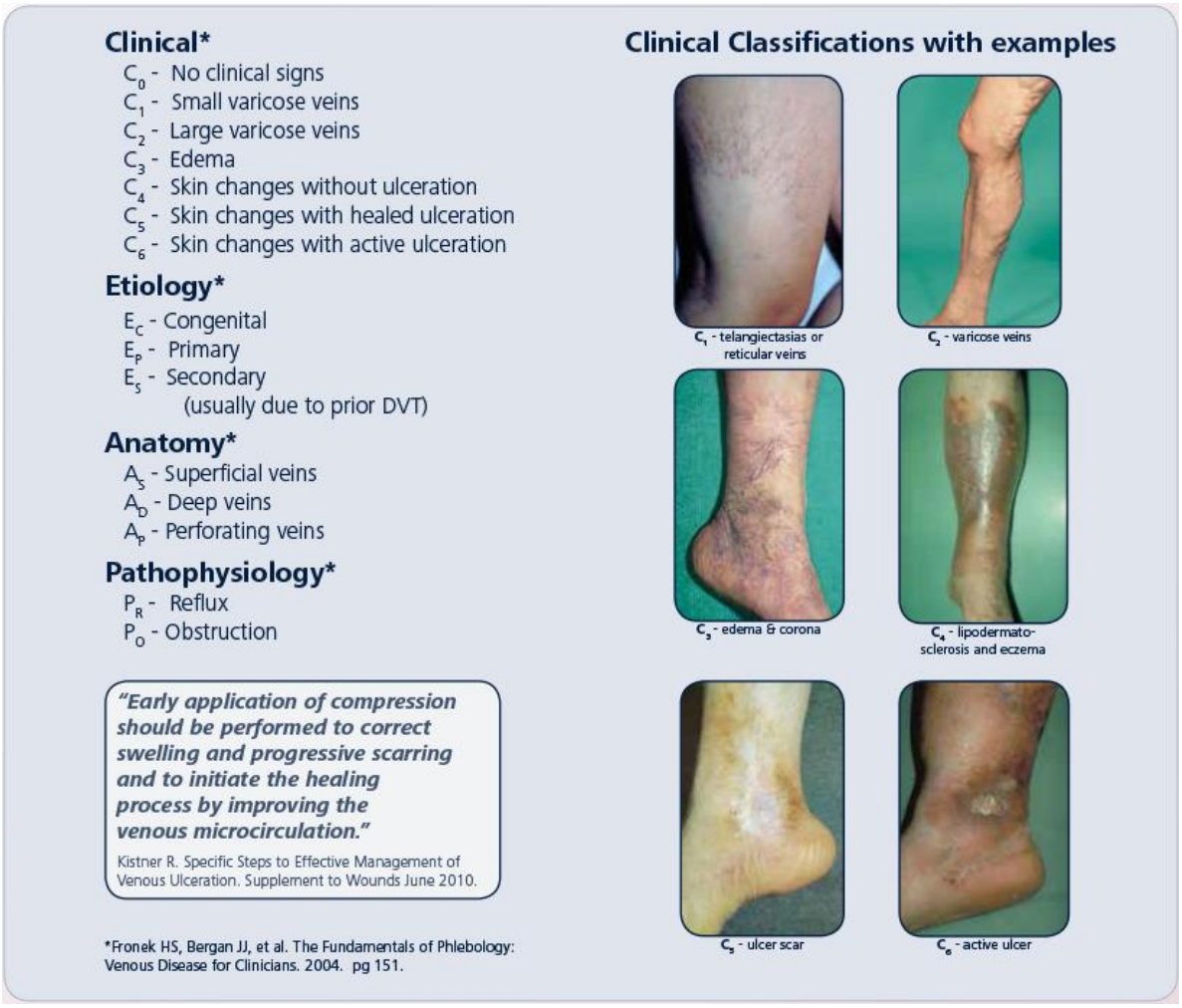
Ulcer Dressing	None ☐ Inadine ☐ Other, details: _____
Baseline Compression	☐ None ☐ KTwo ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking: ☐ Universal 18 ☐ British standard 14-17 ☐ British standard 18-24 ☐ British standard 25-35 ☐ European No EC =18-21 ☐ European No EC =23-32 ☐ European No EC =34-46 ☐ European No EC =>49 ☐ French 10-15 ☐ French 15-20 ☐ French 20-36 ☐ French >36 ☐ American <20 ☐ American 20-30 ☐ American 30-40 ☐ American 40-50
When worn	☐ Day & night ☐ Day only

VISIT 1 (BASELINE) **DUPLEX**

Collect Duplex Report	Email to EVRAtrial@imperial.ac.uk
Trial ulcer Leg ☐ **Right** ☐ **Left** **Date of Scan** Date__ __ / __ __ __ / __ __ __ __ (DD/MMM / YYYY)	
GSV ☐ Incompetent ☐ Occluded AASV Thigh ☐ Incompetent ☐ Occluded PASV Thigh ☐ Incompetent ☐ Occluded AASV Leg ☐ Incompetent ☐ Occluded PASV Leg ☐ Incompetent ☐ Occluded Saphenofemoral Junction ☐ Incompetent ☐ Occluded Thigh (Hunterian) ☐ Incompetent ☐ Occluded Medial Knee (Boyd's) ☐ Incompetent ☐ Occluded Calf (Cockett's) ☐ Incompetent ☐ Occluded Ankle ☐ Incompetent ☐ Occluded PTCV Thigh ☐ Incompetent ☐ Occluded Giacomini Vein ☐ Incompetent ☐ Occluded ATCV Thigh ☐ Incompetent ☐ Occluded SSV ☐ Incompetent ☐ Occluded Interconnecting Vein ☐ Incompetent ☐ Occluded Gluteal ☐ Incompetent ☐ Occluded Sciatic ☐ Incompetent ☐ Occluded Lateral Thigh ☐ Incompetent ☐ Occluded Saphenopopliteal Junction ☐ Incompetent ☐ Occluded Mid-calf ☐ Incompetent ☐ Occluded Para-achilean ☐ Incompetent ☐ Occluded	
Investigations Findings: Deep Veins: Iliac ☐ Reflux ☐ Outflow obstruction Femoral ☐ Reflux ☐ Outflow obstruction Popliteal ☐ Reflux ☐ Outflow obstruction Crural ☐ Reflux ☐ Outflow obstruction	

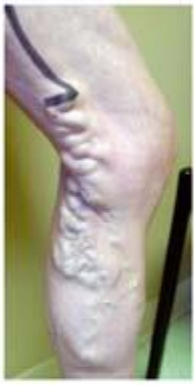
VISIT 1 (BASELINE) **CEAP**

Record in Trial Leg only ☐ **Right** ☐ **Left**	
Clinical Grade	☐ C0 ☐C1 ☐C2 ☐C3 ☐C4 ☐C5 ☐C6
Clinical signs - presentation (C)	☐ Symptomatic ☐ Asymptomatic
Etiologic classification (E)	☐ Primary ☐ Secondary ☐ Congenital ☐ No venous cause
Anatomic distribution (A)	☐ Superficial ☐ Perforator ☐ Deep ☐ No venous cause
Pathophysiologic dysfunction (P)	☐ Reflux ☐ Obstruction ☐ Both ☐No venous cause



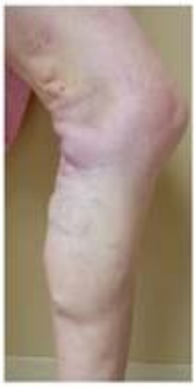
VISIT 1 (BASELINE) **VCSS**

Record in Trial Leg only ☐ Right ☐ Left				
Pain	☐None	☐Mild	☐Moderate	☐Severe
Varicose Veins	☐None	☐Mild	☐Moderate	☐Severe
Venous Edema	☐None	☐Mild	☐Moderate	☐Severe
Skin Pigmentation	☐None	☐Mild	☐Moderate	☐Severe
Inflammation	☐None	☐Mild	☐Moderate	☐Severe
Induration	☐None	☐Mild	☐Moderate	☐Severe
Total no. of ulcers	☐0	☐1	☐2	☐≥3
Active ulcer duration	☐N/A	☐<3 mnts	☐3 to 12 mnths	☐>12mnths
Active ulcer size	☐None	☐<2cm	☐2-6cm	☐>6cm
Compressive therapy	☐None	☐Intermittent	☐Most days	☐Full compliance
Are pedal pulses palpable		☐Yes	☐No	



Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	**Daily**	Daily w/meds
Varicose Veins	None	Few	**Multiple**	Extensive
Venous Edema	None	Evening only	**Afternoon**	Morning
Skin Pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Mod cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	> 1/3 gaiter
No. Active Ulcers	None	1	2	>2
Active Ulcer Size	None	<2 cm	2-6 cm	>6 cm
Ulcer Duration	None	<3 mo	3-12 mo	>1 yr
Compression Therapy	None	Intermittent	**Most days**	Fully comply

Pain=2, VV=2, Edema=2, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. **Total VCSS=8**



Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	**None**	Occasional	Daily	Daily w/meds
Varicose Veins	None	**Few**	Multiple	Extensive
Venous Edema	None	**Evening only**	Afternoon	Morning
Skin Pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Mod cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No. Active Ulcers	None	1	2	>2
Active Ulcer Size	None	<2 cm	2-6 cm	>6 cm
Ulcer Duration	None	<3 mo	3-12 mo	>1 yr
Compression	None	Intermittent	**Most days**	Fully comply

Pain=0, VV=1, Edema=1, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. **Total VCSS=4**

TREATMENT VISIT (THOSE RANDOMISED TO EARLY or COMPRESSION ARM WHO HAVE TREATMENT)

Record in Trial Leg only ☐ **Right** ☐ **Left**

Date of Visit/Procedure: __ __ / __ __ __ / __ __ __ __

(DD / MMM / YYYY)

Type of Anesthesia ☐None ☐Sedation ☐Local ☐Tumescent anesthesia ☐Regional ☐General

Procedural anticoagulation therapy ☐None ☐Warfarin ☐LMWH ☐UFH ☐Other

☐ **N/A Patient did not have laser treatment of any veins (please tick 'none' in this section on INFORM)**

Procedure Endoluminal Laser

(tick only the veins treated by laser in the trial leg)

- ☐ **GSV**
- ☐ **AASV thigh**
- ☐ **PASV thigh**
- ☐ **AASV leg**
- ☐ **PASV leg**
- ☐ **Saphenofemoral junction**
- ☐ **Thigh (Hunterian)**
- ☐ **Medial knee (Boyd's)**
- ☐ **Calf (Cockett's)**
- ☐ **Ankle**
- ☐ **PTCV thigh**
- ☐ **Giacomini vein**
- ☐ **ATCV thigh**
- ☐ **SSV**
- ☐ **Interconnecting vein**
- ☐ **Gluteal**
- ☐ **Sciatic**
- ☐ **Lateral thigh**
- ☐ **Saphenopopliteal junction**
- ☐ **Mid-calf**
- ☐ **Para-achilean**

Procedure Endoluminal Laser

(tick only the veins treated by laser in the trial leg)

Largest diameter of treated vein ___ ___ . ___ **mm**

Site of cannulation:

☐GSV at ankle ☐ GSV at knee ☐SSV at ankle ☐ SSV at mid-calf ☐Other

Power Settings ___ ___ . ___ **watts**

Total Energy Used ___ ___ ___ ___ . ___ **J**

Length of vein treated ___ ___ ___ . ___ **cm**

Pullback time ___ ___ ___ . ___ **secs**

Wavelength:

☐EVL 810 ☐ EVL 940 ☐ EVL 980 ☐EVL 1064 ☐EVL 1319 ☐EVL 1320 ☐EVL 1470

☐ **N/A Patient did not have foam treatment of any veins (please tick 'none' in this section on INFORM)**

Procedure Foam Sclerotherapy (tick only the veins treated by foam in the trial leg)

☐ **GSV**
☐ **AASV thigh**
☐ **PASV thigh**
☐ **AASV leg**
☐ **PASV leg**
☐ **Saphenofemoral junction**
☐ **Thigh (Hunterian)**
☐ **Medial knee (Boyd's)**
☐ **Calf (Cockett's)**
☐ **Ankle**
☐ **PTCV thigh**
☐ **Giacomini vein**
☐ **ATCV thigh**
☐ **SSV**
☐ **Interconnecting vein**
☐ **Gluteal**
☐ **Sciatic**
☐ **Lateral thigh**
☐ **Saphenopopliteal junction**
☐ **Mid-calf**
☐ **Para-achilean**

Procedure Foam Sclerotherapy (tick only the veins treated by foam in the trial leg)

Largest diameter of treated vein ___ ___ . ___ **mm**

Sclerosant Agent: ☐Sodium tetradecyl sulphate ☐Polidocano l ☐Hypertonic saline ☐ Glycerin ☐Other

Sclerosant concentration ___ ___ . ___ **%** **Formulation:** ☐Liquid ☐foam

Total volume of sclerosant ___ ___ . ___**ml**

Liquid to gas ratio ☐1:1 (50%) ☐1:2 (33%) ☐1:3 (25%) ☐1:4 (20%) ☐1:5 (17%)

Gas used: ☐Room air ☐ Gas mix (CO2 & O2) ☐Other

Leg elevated ☐yes ☐No

Patient mobilized ☐0 minutes ☐ 2 minutes ☐ 5 minutes ☐10 minutes; ☐>10 minutes

Ultrasound controlled: ☐yes ☐No

☐ **N/A Patient did not have radiofrequency treatment of any veins (please tick 'none' in this section on INFORM)**

Procedure RF Ablation (tick only the veins treated by RF ablation in the trial leg)

Procedure RF Ablation (tick only the veins treated by RF ablation in the <u>trial</u> leg)

- ☐ **GSV**
- ☐ **AASV thigh**
- ☐ **PASV thigh**
- ☐ **AASV leg**
- ☐ **PASV leg**
- ☐ **Saphenofemoral junction**
- ☐ **Thigh (Hunterian)**
- ☐ **Medial knee (Boyd's)**
- ☐ **Calf (Cockett's)**
- ☐ **Ankle**
- ☐ **PTCV thigh**
- ☐ **Giacomini vein**
- ☐ **ATCV thigh**
- ☐ **SSV**
- ☐ **Interconnecting vein**
- ☐ **Gluteal**
- ☐ **Sciatic**
- ☐ **Lateral thigh**
- ☐ **Saphenopopliteal junction**
- ☐ **Mid-calf**
- ☐ **Para-achilean**

Largest diameter of treated vein ___ ___ . ___ **mm**

Size of cannulation:

☐GSV at ankle ☐ GSV at knee ☐SSV at ankle ☐ SSV at mid-calf ☐Other

catheter size ☐6 F ☐7 F ☐ 8 F ☐Other

Length of vein treated ___ ___ ___ . ___ **cm**

RF Machine ☐RF 85 ☐RF 120 ☐ RF Perf ☐other

Temperature ___ ___ ___ . ___ **°C**

☐ **N/A Patient did not have mechanochemical Ablation of any veins (please tick 'none' in this section on INFORM)** **Mechanochemical Ablation (tick only the veins treated by mechanochemical ablation in the trial leg)**	☐ **GSV** ☐ **AASV thigh** ☐ **PASV thigh** ☐ **AASV leg** ☐ **PASV leg** ☐ **Saphenofemoral junction** ☐ **Thigh (Hunterian)** ☐ **Medial knee (Boyd's)** ☐ **Calf (Cockett's)** ☐ **Ankle** ☐ **PTCV thigh** ☐ **Giacomini vein** ☐ **ATCV thigh** ☐ **SSV** ☐ **Interconnecting vein** ☐ **Gluteal** ☐ **Sciatic** ☐ **Lateral thigh** ☐ **Saphenopopliteal junction** ☐ **Mid-calf** ☐ **Para-achilean** **Mechanochemical Ablation (tick only the veins treated by mechanochemical ablation in the trial leg)** **Length of vein treated** ___ ___ ___ . ___ **cm** **Largest diameter of treated vein** ___ ___ . ___ **mm** **Total volume of sclerosant** ___ ___ . ___**ml** **Type of sclerosant** ☐ Sodium tetradecyl sulphate ☐ Polidocanol ☐ Hypertonic saline ☐ Glycerin ☐ Other: **Sclerosant concentration** ___ ___ . ___ **%**

Was procedure staged?	☐ No ☐ Yes If yes, please complete separate treatment form for each procedure
Was the patient discharged the same day as the operation?	☐ Yes ☐ No: ☐ 1 night in hospital ☐ 2 nights in hospital ☐ 3 nights in hospital ☐ 4 nights in hospital ☐ 5 or more nights in hospital

TREATMENT VISIT (THOSE RANDOMISED TO EARLY or COMPRESSION ARM WHO HAVE TREATMENT)

Length of time in Theatre/treatment room : __ __ __ **mins**

Operation Room ☐Theatre ☐Treatment/clinic room ☐Other, please state_____

Name of person performing intervention _____

Level of person performing intervention ☐Consultant ☐Registrar ☐Other please state_____

Anesthetic used: ☐General ☐Local

TREATMENT VISIT (THOSE RANDOMISED TO EARLY or COMPRESSION ARM WHO HAVE TREATMENT) POST PROCEDURE **COMPRESSION (TO 1 WEEK)**

Baseline Compression	☐ None ☐ KTwo ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking: ☐ Universal 18 ☐ British standard 14-17 ☐ British standard 18-24 ☐ British standard 25-35 ☐ European No EC =18-21 ☐ European No EC =23-32 ☐ European No EC =34-46 ☐ European No EC =>49 ☐ French 10-15 ☐ French 15-20 ☐ French 20-36 ☐ French >36 ☐ American <20 ☐ American 20-30 ☐ American 30-40 ☐ American 40-50
When worn	☐ Day & night ☐ Day only
Ulcer Dressing	None ☐ Inadine ☐ Other, details: _____

(THOSE RANDOMISED TO EARLY or COMPRESSION ARM WHO HAVE TREATMENT)POST PROCEDURE **COMPRESSION (AFTER 1 WEEK)**

Baseline Compression	☐ None ☐ KTwo ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking: ☐ Universal 18 ☐ British standard 14-17 ☐ British standard 18-24 ☐ British standard 25-35 ☐ European No EC =18-21 ☐ European No EC =23-32 ☐ European No EC =34-46 ☐ European No EC =>49 ☐ French 10-15 ☐ French 15-20 ☐ French 20-36 ☐ French >36 ☐ American <20 ☐ American 20-30 ☐ American 30-40 ☐ American 40-50
When worn	☐ Day & night ☐ Day only
Ulcer Dressing	None ☐ Inadine ☐ Other, details: _____

After Treatment

		Yes	No
1.	**Were there any adverse events related to the procedure?** (If yes, please record on Adverse Events Form)	☐	☐
2.	**Were there any serious adverse events?** (If yes, please record on Serious Adverse Events Form)	☐	☐

TELEPHONE FOLLOW UP – PATIENT CONTACT ATTEMPT FORM

Please document all attempts to contact the patient during the 12 month follow-up period	If you could not speak to the patient on this attempt, please document if message left with relative / voicemail / number no longer works etc.
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	
Date of Call __ __ / __ __ __ / _2_ 0 __ __ (DD / MMM / YYYY) **Time of call:** __ __ : __ __ **(24:00)** **Month No. ____ call**	

TELEPHONE FOLLOW UP – MONTH 1,2,3,4,5,7,8,9,10,11
BASIC INFORMATION

Date of Call __ __ / __ __ __ / __ __ __ __ (DD / MMM / YYYY) **Time of call: __ __ : __ __ (24:00)**	
Is the patient alive?	☐ Yes ☐ No **If no date of death:__ __ / __ __ __ / _2 _0 __ __**
Has the ulcer healed?	☐ Yes ☐ No IF YES ARRANGE URGENT VERIFICATION VISIT
Change of dressing type since last spoken?	☐ Yes If yes dressing change: ☐ Bandage to Stocking ☐ Stocking to Bandage ☐ No longer wearing stocking ☐ Other: ☐ Unknown ☐ No
Currently Anticoagulants taking therapy	☐ **None** ☐ **Warfarin** ☐ **New Oral Anticoagulants: _____** ☐ **Other: _____**
Currently taking Antiplatelet therapy	☐ **None** ☐ **Aspirin** ☐ **Clopidogrel** ☐ **Other: _____**
Currently taking Steroids	☐ Yes ☐ No
Currently taking Trental (pentoxyfilne)	☐ Yes ☐ No

Were there any adverse events related to the procedure/ compression in the last month? (If yes, please record on Adverse Events Form)	☐No	☐Yes
Were there any serious adverse events in the last month? (If yes, please record on Serious Adverse Events Form)	☐No	☐Yes

Where in the community will the patient be followed-up? e.g. Name of GP / Community Nurse_____

Which NHS Trust or Former PCT will this follow up occur in?_____

TELEPHONE FOLLOW UP – MONTH 1,2,3,4,5,7,8,9,10,11 RESOURCE USE

Please record the reason for EACH visit and any treatment received. Enter each separate entry under the appropriate tab so every visit is accounted for.

Since last call how many **hospital admissions** has the patient had? (Please complete Admission Details section) Total number _____ (enter 0 if none)	Reason for admission (if known)_____ Treatment or procedure received (if known)_____ No. nights spent in hospital_____ Reason for admission (if known)_____ Treatment or procedure received (if known)_____ No. nights spent in hospital_____
Since last call how many **outpatient hospital visits** has the patient made to the hospital (including routine follow-up while participating in the trial) (Please complete Outpatient Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
3.* Since last call how many **visits to your GP** to see the doctor has the patient made? (Please complete GP Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____

4.* Since last call how many **home visits from your GP** has the patient had? (Please complete Home Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
5.* Since last call how many **visits to the district nurse** has the patient had? (Please complete To District Nurse section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
6.* Since last call how **many home visits from the district nurse** has the patient had? (Please complete From District Nurse section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
7.* In the last month how **many occupational therapy visits** (covered by NHS) has the patient had? (Please complete Occupational Therapy Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____

8.* In the last month how many **physiotherapy visits** (covered by NHS) has the patient had? (Please complete Physiotherapy Visit section Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
9.* In the last month has the patient had to **buy anything out of your own pocket** (>£5) to help with the leg ulcer? e.g. specialist equipment, pharmacy, private physiotherapy ☐ No ☐ Yes	If yes, please provide details: _____ How much did this cost? _____(£)
10.* Since last call how many **days of carer help** has the patient had? Total number _____ (enter 0 if none)	
11.* Since last call how many **days of home help** has the patient had? Total number _____ (enter 0 if none)	
12.* Since last call how many days of **unpaid carer time** e.g. from a friend or relative has the patient had? Total number _____ (enter 0 if none)	
13.* Since last call how many **days has the patient had to take off work** due to the leg ulcer? Total number _____ (enter 0 if none)	
14.* Since last call how many **days of normal activity has the patient lost** due to the leg ulcer? Total number _____ (enter 0 if none)	

TELEPHONE FOLLOW UP – MONTH 1,2,3,4,5,7,8,9,10,11
EXTRA QUESTIONS IF ULCER HAS HEALED

If patient has healed during f/u and verification visit has taken place	
Has the ulcer reoccurred since healing?	☐ No ☐ Yes if yes: **Date of reoccurance:**__ __ / __ __ __ / _2 _0 __ __
Are you still wearing compression	☐ None ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking
Did you have any further interventional treatment?	☐ None ☐ Thermal ablation ☐ Foam sclerotherapy ☐ Surgery ☐ Other: _____
If the ulcer reoccurred, did the new ulcer heal?	☐ Yes if yes: **Date of new ulcer healing:**__ __ / __ __ __ / _2 _0 __ __ ☐ No ☐ N/A – Ulcer has not reoccurred

TELEPHONE FOLLOW UP – MONTH 6 & 12
BASIC INFORMATION

Date of Call __ __ / __ __ __ / __ __ __ __ (DD / MMM / YYYY) **Time of call: __ __ : __ __ (24:00)**	
Is the patient alive?	☐ Yes ☐ No
Has the ulcer healed?	☐ Yes ☐ No
Change of dressing type?	☐ No ☐ Yes If yes, dressing type: ☐ Bandage to Stocking ☐ Stocking to Bandage ☐ No longer wearing stocking ☐ Other: ☐ Unknown
Currently taking Antiplatelet therapy	☐ **None** ☐ **Aspirin** ☐ **Clopidogrel** ☐ **Other:** _____
Currently Anticoagulants taking therapy	☐ **None** ☐ **Warfarin** ☐ **New Oral Anticoagulants:** _____ ☐ **Other:** _____
Currently taking Steroids	☐ Yes ☐ No
Currently taking Trental (pentoxyfilne)	☐ Yes ☐ No

Were there any adverse events related to the procedure/ compression in the last month? (If yes, please record on Adverse Events Form)	☐No	☐Yes
Were there any serious adverse events in the last month? (If yes, please record on Serious Adverse Events Form)	☐No	☐Yes

TELEPHONE FOLLOW UP – MONTH 6 & 12
RESOURCE USE

Please record the reason for EACH visit and any treatment received. Enter each separate entry under the appropriate tab so every visit is accounted for.

Since last call how many **hospital admissions** has the patient had? (Please complete Admission Details section) Total number _____ (enter 0 if none)	Reason for admission (if known)_____ Treatment or procedure received (if known)_____ No. nights spent in hospital_____ Reason for admission (if known)_____ Treatment or procedure received (if known)_____ No. nights spent in hospital_____
Since last call how many **outpatient visits** has the patient made to the hospital (including routine follow-up while participating in the trial) (Please complete Outpatient Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
3.* Since last call how many **visits to your GP** to see the doctor has the patient made? (Please complete GP Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____

4.* Since last call how many **home visits from your GP** has the patient had? (Please complete Home Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
5.* Since last call how many **visits to the district nurse** has the patient had? (Please complete To District Nurse section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
6.* Since last call how many **home visits from the district nurse** has the patient had? (Please complete From District Nurse section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
7.* In the last month how many **occupational therapy visits** (covered by NHS) has the patient had? (Please complete Occupational Therapy Visit section) Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____

8.* In the last month how many **physiotherapy visits** (covered by NHS) has the patient had? (Please complete Physiotherapy Visit section Total number _____ (enter 0 if none)	Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____ Reason for visit (if known)_____ Treatment or procedure received (if known)_____
9.* In the last month has the **patient had to buy anything out of your own pocket** (>£5) to help with the leg ulcer? e.g. specialist equipment, pharmacy, private physiotherapy ☐ No ☐ Yes	If yes, please provide details: _____ How much did this cost? _____(£)
10.* Since last call how many **days of carer help** has the patient had? Total number _____ (enter 0 if none)	
11.* Since last call how many **days of home help** has the patient had? Total number _____ (enter 0 if none)	
12.* Since last call how many days **of unpaid carer time** e.g. from a friend or relative has the patient had? Total number _____ (enter 0 if none)	
13.* Since last call how many **days has the patient had to take off work** due to the leg ulcer? Total number _____ (enter 0 if none)	
14.* Since last call how many **days of normal activity has the patient lost** due to the leg ulcer? Total number _____ (enter 0 if none)	

TELEPHONE FOLLOW UP – MONTH 6 & 12
REMIND PATIENT TO COMPLETE POSTAL QUESTIONAIRES FOR 6 & 12 MONTHS

SF-36

AVVQ

EQ-5D

If the patient has returned the questionnaires and they have gaps obtain the missing information over the telephone call.

TELEPHONE FOLLOW UP – MONTH 6 & 12
EXTRA QUESTIONS IF ULCER HAS HEALED

If patient has healed during this month's f/u and verification visit has taken place	
Has the ulcer reoccurred since healing?	☐ No ☐ Yes if yes: **Date of reoccurance:**__ __ / __ __ __ / _2 _0 __ __
Are you still wearing compression	☐ None ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking
Did you have any further interventional treatment?	☐ None ☐ Thermal ablation ☐ Foam sclerotherapy ☐ Surgery ☐ Other: _____
If the ulcer reoccurred, did the new ulcer heal?	☐ Yes if yes: **Date of new ulcer healing:**__ __ / __ __ __ / _2 _0 __ __ ☐ No ☐ N/A – Ulcer has not reoccurred

6 WEEK CLINIC VISIT
CLINIC INFORMATION

BASIC INFORMAT **Is the patient alive?**	☐ Yes ☐ No if no **Date of death:** __ __ / __ __ __ / _2 _0 __ __
Has the ulcer healed?	☐ Yes ☐ No
What is the current compression regime	☐ None ☐ KTwo ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking
What is the future compression regime post visit	☐ None ☐ Three-layer bandage ☐ Four-layer bandage ☐ European short stretch ☐ Stocking
Has Duplex Scan been taken?	☐ Yes ☐ No _____ ☐ N/A Delayed treatment
Take Photo	Save as: PtTrialnumber_6week_Photo_dd/mm/yy Email to EVRAtrial@imperial.ac.uk
Size (from tracing)	_____ cm2 Scan tracing, save as: PtTrialnumber_6week_tracing_dd/mm/yy Email to EVRAtrial@imperial.ac.uk

Currently taking Antiplatelet therapy	☐ **None** ☐ **Aspirin** ☐ **Clopidogrel** ☐ **Other:** _____
Currently Anticoagulants taking therapy	☐ **None** ☐ **Warfarin** ☐ **New Oral Anticoagulants:** _____ ☐ **Other:** _____
Currently taking Steroids	☐ Yes ☐ No
Currently taking Trental (pentoxyfilne)	☐ Yes ☐ No

		Yes	**No**
1.	**Were there any adverse events related to the treatment?** (If yes, please record on Adverse Events Form)	☐	☐
2.	**Were there any serious adverse events?** (If yes, please record on Serious Adverse Events Form)	☐	☐

6 WEEK CLINIC VISIT:
DUPLEX (EARLY TREATMENT ARM ONLY)

Collect Duplex Report	Email to EVRAtrial@imperial.ac.uk
Trial ulcer Leg ☐ **Right** ☐ **Left** **Date of Scan** Date__ __ / __ __ __ / __ __ __ __ (DD/MMM / YYYY)	
GSV ☐ Incompetent ☐ Occluded **AASV Thigh** ☐ Incompetent ☐ Occluded **PASV Thigh** ☐ Incompetent ☐ Occluded **AASV Leg** ☐ Incompetent ☐ Occluded **PASV Leg** ☐ Incompetent ☐ Occluded **Saphenofemoral Junction** ☐ Incompetent ☐ Occluded **Thigh (Hunterian)** ☐ Incompetent ☐ Occluded **Medial Knee (Boyd's)** ☐ Incompetent ☐ Occluded **Calf (Cockett's)** ☐ Incompetent ☐ Occluded **Ankle** ☐ Incompetent ☐ Occluded **PTCV Thigh** ☐ Incompetent ☐ Occluded **Giacomini Vein** ☐ Incompetent ☐ Occluded **ATCV Thigh** ☐ Incompetent ☐ Occluded **SSV** ☐ Incompetent ☐ Occluded **Interconnecting Vein** ☐ Incompetent ☐ Occluded **Gluteal** ☐ Incompetent ☐ Occluded **Sciatic** ☐ Incompetent ☐ Occluded **Lateral Thigh** ☐ Incompetent ☐ Occluded **Saphenopopliteal Junction** ☐ Incompetent ☐ Occluded **Mid-calf** ☐ Incompetent ☐ Occluded **Para-achilean** ☐ Incompetent ☐ Occluded	
Investigations Findings: Deep Veins: **Iliac** ☐ Reflux ☐ Outflow obstruction **Femoral** ☐ Reflux ☐ Outflow obstruction **Popliteal** ☐ Reflux ☐ Outflow obstruction **Crural** ☐ Reflux ☐ Outflow obstruction	
Evidence of Reflux: ☐ Yes ☐ No	

Are all ablated segments occluded? ☐ **Yes** ☐ **No** **If no, which veins have reopened:** ☐ **GSV** ☐ **AASV thigh** ☐ **PASV thigh** ☐ **AASV leg** ☐ **PASV leg Saphenofemoral junction** ☐ **Thigh (Hunterian)** ☐ **Medial knee (Boyd's)** ☐ **Calf (Cockett's)** ☐ **Ankle** ☐ **PTCV thigh** ☐ **Giacomini vein** ☐ **ATCV thigh** ☐ **SSV** ☐ **Interconnecting vein** ☐ **Gluteal** ☐ **Sciatic** ☐ **Lateral thigh** ☐ **Saphenopopliteal junction** ☐ **Mid-calf** ☐ **Para-achilean**	

6 WEEK CLINIC VISIT: **CEAP**

Record in Trial Leg only	
Clinical Grade	☐ C0 ☐C1 ☐C2 ☐C3 ☐C4 ☐C5 ☐C6
Clinical signs - presentation (C)	☐ Symptomatic ☐ Asymptomatic
Etiologic classification (E)	☐ Primary ☐ Secondary ☐ Congenital ☐ No venous cause
Anatomic distribution (A)	☐ Superficial ☐ Perforator ☐ Deep ☐ No venous cause
Pathophysiologic dysfunction (P)	☐ Reflux ☐ Obstruction ☐ Both ☐No venous cause

Clinical*

C_0 - No clinical signs
C_1 - Small varicose veins
C_2 - Large varicose veins
C_3 - Edema
C_4 - Skin changes without ulceration
C_5 - Skin changes with healed ulceration
C_6 - Skin changes with active ulceration

Etiology*

E_C - Congenital
E_P - Primary
E_S - Secondary
(usually due to prior DVT)

Anatomy*

A_S - Superficial veins
A_D - Deep veins
A_P - Perforating veins

Pathophysiology*

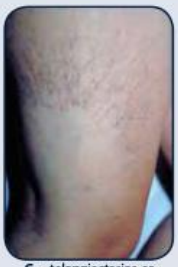
P_R - Reflux
P_O - Obstruction

"Early application of compression should be performed to correct swelling and progressive scarring and to initiate the healing process by improving the venous microcirculation."

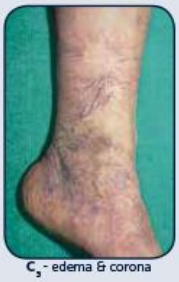
Kistner R. Specific Steps to Effective Management of Venous Ulceration. Supplement to Wounds June 2010.

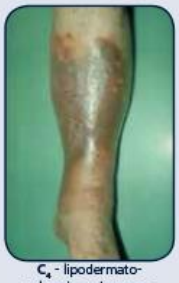
*Fronek HS, Bergan JJ, et al. The Fundamentals of Phlebology: Venous Disease for Clinicians. 2004. pg 151.

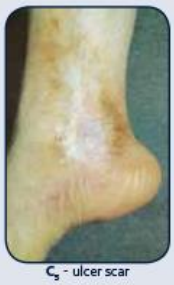
Clinical Classifications with examples

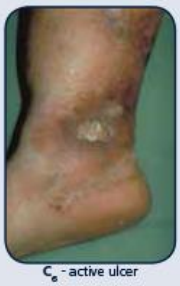

C_1 - telangiectasias or reticular veins


C_2 - varicose veins


C_3 - edema & corona

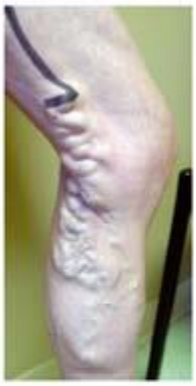

C_4 - lipodermato-sclerosis and eczema


C_5 - ulcer scar


C_6 - active ulcer

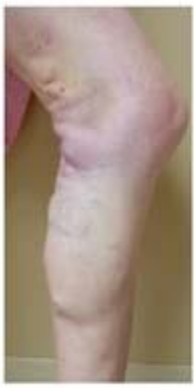
6 WEEK CLINIC VISIT: **VCSS**

Record in Trial Leg only				
Pain	☐None	☐Mild	☐Moderate	☐Severe
Varicose Veins	☐None	☐Mild	☐Moderate	☐Severe
Venous Edema	☐None	☐Mild	☐Moderate	☐Severe
Skin Pigmentation	☐None	☐Mild	☐Moderate	☐Severe
Inflammation	☐None	☐Mild	☐Moderate	☐Severe
Induration	☐None	☐Mild	☐Moderate	☐Severe
Total no. of ulcers	☐0	☐1	☐2	☐≥3
Active ulcer duration	☐N/A	☐<3 mnts	☐3 to 12 mnths	☐>12mnths
Active ulcer size	☐None	☐<2cm	☐2-6cm	☐>6cm
Compressive therapy	☐None	☐Intermittent	☐Most days	☐Full compliance
Are pedal pulses palpable		☐Yes	☐No	



Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	**Daily**	Daily w/meds
Varicose Veins	None	Few	**Multiple**	Extensive
Venous Edema	None	Evening only	**Afternoon**	Morning
Skin Pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Mod cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	> 1/3 gaiter
No. Active Ulcers	None	1	2	>2
Active Ulcer Size	None	<2 cm	2-6 cm	>6 cm
Ulcer Duration	None	<3 mo	3-12 mo	>1 yr
Compression Therapy	None	Intermittent	**Most days**	Fully comply

Pain=2, VV=2, Edema=2, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. **Total VCSS=8**



Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	**None**	Occasional	Daily	Daily w/meds
Varicose Veins	None	**Few**	Multiple	Extensive
Venous Edema	None	**Evening only**	Afternoon	Morning
Skin Pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Mod cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No. Active Ulcers	None	1	2	>2
Active Ulcer Size	None	<2 cm	2-6 cm	>6 cm
Ulcer Duration	None	<3 mo	3-12 mo	>1 yr
Compression	None	Intermittent	**Most days**	Fully comply

Pain=0, VV=1, Edema=1, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. **Total VCSS=4**

6 WEEK CLINIC VISIT:
PATIENT TO COMPLETE HEALTH QUESTIONAIRES AT 6 WEEK CLINIC VISIT

SF-36

AVVQ

EQ-5D

ULCER HEALED

Date patient informed site ulcer was healed
. (Also date of visit) __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

WEEK 1

Date of verification visit
. __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

Photographic evidence has been sent to the trials unit: ☐Yes ☐No (SEND NOW!)

Date of the photo
. __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

WEEK 2

Photographic evidence has been sent to the trials unit: ☐Yes ☐No (SEND NOW!)

Date of the photo
. __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

WEEK 3

Photographic evidence has been sent to the trials unit: ☐Yes ☐No (SEND NOW!)

Date of the photo
. __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

WEEK 4

Photographic evidence has been sent to the trials unit: ☐Yes ☐No (SEND NOW!)

Date of the photo
. __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

ADVERSE EVENT FORM

Adverse Event Description	**Systemic** ☐ Allergic reaction requiring local or no treatment ☐ Migraine ☐ Visual disturbance ☐ Fainting ☐ Cough / chest tightness ☐ Systemic infection ☐ PE ☐ TIA ☐ Stroke ☐ Other: _____ **Local** ☐ Bleeding requiring intervention ☐ Blistering of skin ☐ Pressure damage ☐ Nerve damage ☐ DVT ☐ Hematoma ☐ Patient reported parathesia ☐ Pigmentation of skin ☐ Superficial thrombophlebitis ☐ New ulcer ☐ Deterioration of ulcer ☐ Wound infection ☐ Other: _____
Onset Date	__ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Ongoing	☐ Yes ☐ No: end date __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Treatment for AE	_Please state_____
Outcome	☐ Recovered ☐ Not yet recovered ☐ Death ☐ Unknown
AE Additional Details	Please state_____ _____ _____

SERIOUS ADVERSE EVENT FORM

Serious Adverse Event Description	**Please state**_____
Serious reason	☐Death ☐Life threatening ☐ Persistently disabling ☐Hospitalisation required ☐Congenital abnormality ☐Other medical important event: detail_____
Onset Date	__ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Ongoing	☐Yes ☐No: end date __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Treatment for SAE	_Please state_____
Frequency	☐Single Episode ☐Intermittent ☐Frequent ☐Continuous ☐Unknown
Severity	☐ Mild (aware of it easily tolerated) ☐ Moderate (discomfort/interference with usual activity) ☐ Severe (inability to carry out normal activity) ☐ Life threatening or disabling
Relationship to procedure or compression (PI MUST ASSESS RELATIONSHIP)	☐**Not related** (no evidence of a causal relationship between procedure/compression and event). ☐**Unlikely** (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment). ☐**Possible** (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) ☐**Probable** (there is evidence to suggest a causal relationship. Other factors are unlikely. ☐**Definite** (there is clear evidence to suggest a causal relationship. Other factors can be ruled out)
Outcome	☐Recovered ☐Not yet recovered ☐Death ☐Unknown
Expectedness in relation to procedure or compression	☐Expected ☐Unexpected **(PI MUST ASSESS EXPECTEDNESS)**
Principle Investigator Signature (to confirm review and assessment of SAE)	_PI SIGN_____DATE_____

PROTCOL DEVIATION FORM

☐ Patients randomised to multilayer compression plus early venous reflux ablation, who receive endovenous intervention more than two weeks from randomisation selected, please complete the reason why:

- ☐ Patient unable to attend treatment visit
- ☐ Hospital cannot book in patient

☐ Patients who are non-compliant with compression bandaging, defined as use <75% of the prescribed duration, please complete reason why:

- ☐ Patient found compression treatment too uncomfortable / painful
- ☐ Patient did not attend clinic for changes

☐ Patients randomised to compression bandaging alone who undergo endovenous ablation prior to verified healing, please complete reason why:

- ☐ Ulcer deterioration
- ☐ Other:_____

What interventional treatment did the patient have:

- ☐ None
- ☐ Thermal ablation
- ☐ Foam sclerotherapy
- ☐ Surgery
- ☐ Other:_____

☐ Other (please detail)_____

_____

_____

TRIAL COMPLETION / END OF STUDY

Did participant complete the trial?	☐ **Yes:** ☐**1 Year Post Randomisation reached ulcer not healed** ☐**Ulcer Healed** ☐ **No,** Please provide **date of termination** and complete below: __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)

Termination Reason: please tick most appropriate reason for participant not completing the trial:

☐ **Serious Adverse Effect:** please state related SAE: _____

☐ **Termination of study by sponsor**

☐ **Investigator's decision, specify: _____**

☐ **Inability or subject failure to comply with protocol**

☐ **Subject Withdrew / Lost to follow up**

☐ **Death**

☐ **Other, specify:** _____

Health Questionnaire –EQ-5D

English version for the UK
(validated for Ireland)

The EQ-5D form must be completed at baseline and then at 6 weeks, 6 months and 12 months.

Please tick the relevant box to indicate:

Baseline ☐
6 week follow-up ☐

6-month follow-up ☐
12-month follow-up ☐

Date of questionnaire completion: ☐☐ ☐☐ ☐☐ **dd/mm/yy**

EVRA Trial ID ☐☐☐

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

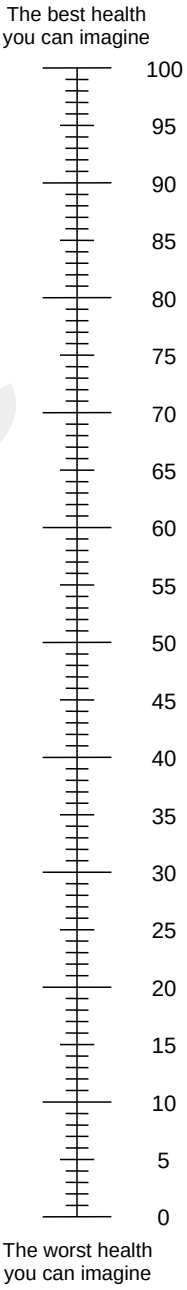
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Aberdeen Varicose Veins Questionnaire (AVVQ)

The AVVQ form must be completed at baseline and then at 6 weeks, 6 months and 12 months.

Please tick the relevant box to indicate:

Baseline ☐

6 week follow-up ☐

6-month follow-up ☐

12-month follow-up ☐

Date of questionnaire completion: ☐☐ ☐☐ ☐☐ **dd/mm/yy**

EVRA Trial ID ☐☐☐

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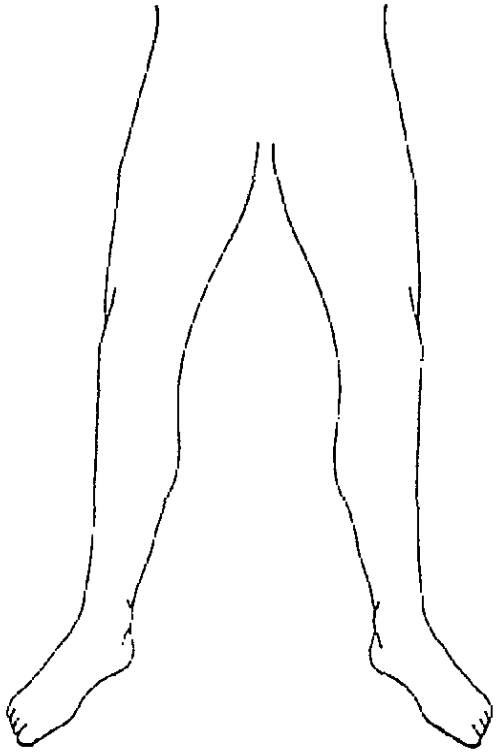
Please answer all 13 questions

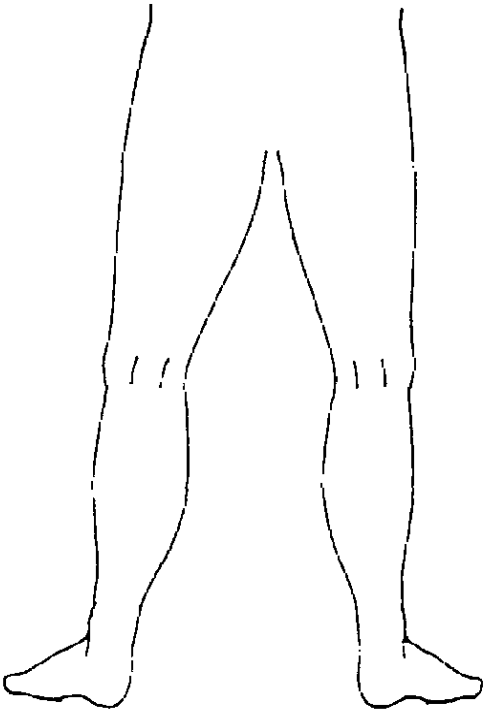
YOUR VARICOSE VEINS

1. Please draw in your varicose veins in the diagram(s) below:-

Legs viewed from front



Legs viewed from back



2. In the last two weeks, for how many days did your varicose veins cause you pain or ache?
(Please tick one box for each leg)

	R Leg	L Leg
None at all	☐	☐
Between 1 and 5 days	☐	☐
Between 6 and 10 days	☐	☐
For more than 10 days	☐	☐

3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?

(Please tick one box)

None at all	☐
Between 1 and 5 days	☐
Between 6 and 10 days	☐
For more than 10 days	☐

4. In the last two weeks, how much ankle swelling have you had?

(Please tick one box)

None at all	☐
Slight ankle swelling	☐
Moderate ankle swelling (eg. causing you to sit with your feet up whenever possible)	☐
Severe ankle swelling (eg. causing you difficulty putting on your shoes)	☐

5. In the last two weeks, have you worn support stockings or tights?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes, those I bought myself without a doctor's prescription	☐	☐
Yes, those my doctor prescribed for me which I wear occasionally	☐	☐
Yes, those my doctor prescribed for me which I wear every day	☐	☐

6. In the last two weeks, have you had any itching in association with your varicose veins?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes, but only above the knee	☐	☐
Yes, but only below the knee	☐	☐
Both above and below the knee	☐	☐

7. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes	☐	☐

8. Do you have a rash or eczema in the area of your ankle?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐

	R Leg	L Leg
Yes, but it does not require any treatment from a doctor or district nurse	☐	☐
Yes, and it requires treatment from my doctor or district nurse	☐	☐

9. Do you have a skin ulcer associated with your varicose veins?
(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes	☐	☐

10. Does the appearance of your varicose veins cause you concern?
(Please tick one box)

- ☐ No
- ☐ Yes, their appearance causes me slight concern
- ☐ Yes, their appearance causes me moderate concern
- ☐ Yes, their appearance causes me a great deal of concern

11. Does the appearance of your varicose veins influence your choice of clothing including tights?
(Please tick one box)

- ☐ No
- ☐ Occasionally
- ☐ Often
- ☐ Always

12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities?
(Please tick one box)

- ☐ No
- ☐ I have been able to work but my work has suffered to a slight extent
- ☐ I have been able to work but my work has suffered to a moderate extent
- ☐ My veins have prevented me from working one day or more

13. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)?
(Please tick one box)

- ☐ No
- ☐ Yes, my enjoyment has suffered to a slight extent
- ☐ Yes, my enjoyment has suffered to a moderate extent
- ☐ Yes, my veins have prevented me taking part in any leisure activities