FOCUS trial RANDOMISATION FORM

Please use a black pen & PRINT IN CAPITALS
Please complete this form on the day of randomisation.
Randomisation MUST be done via the FOCUS website (www.focustrial.org.uk)
You MUST complete this form before logging on to the randomisation system.

Today's date (dd/mm/yyyy): ...../...../..... Collaborating Site: .....

Randomising Person: ..... Signature: .....

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1. IS THE PATIENT ELIGIBLE?

Inclusion criteria

- ☐ Age ≥ 18 years
- ☐ Clinical diagnosis of stroke 2-15 days previously (Day of stroke onset = Day 0, randomise on Day 2-15)
- ☐ Brain imaging consistent with intracerebral haemorrhage or ischaemic stroke. A normal CT is compatible with a diagnosis of ischaemic stroke
- ☐ Persisting focal neurological deficit is present at the time of randomisation severe enough to warrant treatment from the patient's or carer's perspective. Is the patient (or carer) willing for the patient to take tablets for 6 months to help recovery?

Exclusion criteria

- ☐ Subarachnoid haemorrhage (unless secondary to intracerebral haemorrhage)
- ☐ Unlikely to be available for follow-up for the next 12 months e.g. no fixed home address
- ☐ Unable to speak English AND no close family member available to help with follow up forms
- ☐ Other life threatening illness (e.g. advanced cancer) that will make 12-month survival unlikely
- ☐ History of epileptic seizures
- ☐ History of allergy to Fluoxetine
- ☐ Contraindications to Fluoxetine including:
  - hepatic impairment (ALT > 3 upper normal limit),
  - renal impairment (Creatinine >180 micromol/l),
- ☐ Pregnant or breast-feeding, women of child bearing age not taking contraception. Minimum contraception is an oral contraceptive
- ☐ Previous drug overdose or attempted suicide?
- ☐ Current or recent (within the last month) depression requiring treatment with an SSRI antidepressant
- ☐ Current use, or during the last 5 weeks, of a monoamine oxidase inhibitor (MAOI) (e.g. selegiline), or current use of any other medications which have serious interaction with Fluoxetine (e.g. **Metoprolol for heart failure**, Pimozide, St Johns Wort)*
  **The web based randomisation system will check for potentially serious drug interactions when the current concomitant medication is entered on Page 2*
- ☐ Currently participating in another trial of a medicinal product (CTIMP)(e.g. SOS, ENOS, DARS)

Name of PI/sub-investigator who has confirmed eligibility: .....

Has the PI or sub-investigator signed the recruitment sticker and is it stuck in the medical notes? YES ☐ NO ☐

Is the patient currently a hospital inpatient? Yes ☐ No ☐

If **YES**, what ward/unit are they on: _____

2. CONSENT

Which version of the patient information leaflet was given? Traditional ☐ Easy access ☐ Both ☐

Has written informed consent been obtained? Yes ☐ No ☐

Date consent obtained (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Who gave consent? Patient ☐ Proxy ☐

Name of person giving consent (if not patient): _____ Relationship to patient: _____

Consent obtained by (name): _____

Have you FAXED the signed consent form to 0131 242 7742? Yes ☐ No ☐ (If no please fax this now.)

3. PATIENT DETAILS

Patient's Forename: _____ Family name: _____

Gender: Male ☐ Female ☐

Date of Birth (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

Ethnicity: White ☐ Black ☐
Asian ☐ Chinese ☐
Other ☐ Please specify _____

NHS Number (E, W & NI): ☐☐☐ ☐☐☐ ☐☐☐☐

CHI number (Scotland): ☐☐☐☐☐☐☐☐☐☐

Marital Status: Married ☐ Single ☐
Widowed ☐ Separated/Divorced ☐
Partner ☐ Other ☐

Living Arrangements: Living Alone ☐ Institutional living ☐
Living with someone else ☐ Other ☐

Employment: Full time ☐ Part time ☐
Voluntary ☐ Retired ☐
Unemployed or Disabled ☐ Other ☐

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4. CO-MORBIDITIES (BASED ON PATIENT'S REPORT AND MEDICAL NOTES)

i. Depression (requiring antidepressants or referral to psychiatrist/psychologist)
   a. Previous depression? Yes ☐ No ☐ Unknown ☐
   b. Current depression? Yes ☐ No ☐ Unknown ☐

ii. History of Diabetes Yes ☐ No ☐ Unknown ☐

iii. Previous Coronary Heart Disease (i.e. definite angina, MI, CABG, coronary stenting) Yes ☐ No ☐ Unknown ☐

iv. Previous ischaemic stroke/TIA or stroke of uncertain pathology (before this event) Yes ☐ No ☐ Unknown ☐

v. Previous Intracranial bleeding (including prior haemorrhagic stroke or subdural) Yes ☐ No ☐ Unknown ☐

vi. Past history of upper gastrointestinal bleeding Yes ☐ No ☐ Unknown ☐

vii. Current or past Hyponatraemia (Na <130mmol/l) Yes ☐ No ☐ Unknown ☐

viii. Bone Fractures Yes ☐ No ☐ Unknown ☐

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5. CURRENT MEDICATIONS (PLEASE PRINT NAMES ONLY):

1.	6.	11.
2.	7.	12
3.	8.	13.
4.	9.	14
5.	10	15

6. INFORMATION ABOUT THIS STROKE

Date of stroke onset (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐

	National Institute of Health Stroke Score (NIHSS):	**Score**
1a.	**Level of Consciousness** 0: Alert 1: Not alert, but arousable with minimal stimulation 2: Not alert, requires repeated stimulation to attend 3: Coma (makes at best only reflex movements to pain)	
1b.	**LOC questions** (ask patient the month & her/his age) 0: Answers both correctly 1: Answers one correctly (score 1 if patients speech affected other by than aphasia) 2: Both incorrect	
1c.	**LOC commands** (ask patient to open/close eyes & form/release a fist) 0: Obeys both correctly 1: Obeys one correctly 2: Both incorrect	
2.	**Best gaze** (only horizontal eye movements) 0: Normal 1: Partial gaze palsy (can be overcome) or single nerve palsy (III, IV or VI) 2: Total gaze paresis or Forced deviation (cannot be overcome with rapid head turn)	
3.	**Visual field testing** 0: No visual field loss 1: Partial hemianopia (including quadrantanopia or visual extinction (see 11)) 2: Complete hemianopia 3: Bilateral hemianopia (including bilateral blindness from any cause)	
4.	**Facial Paresis** (ask patient to show teeth/raise eyebrows & close eyes tightly) 0: Normal symmetrical movement 1: Minor paralysis (flattened nasolabial fold, asymmetry on smiling) 2: Partial paralysis (total or near total paralysis of lower face) 3: Complete paralysis of one or both sides (absence of facial movement in the upper & lower face)	
5.	**Motor function – Arm** 0: Normal (extends arms 90^0 (or 45^0) position for 5 seconds without drift) *Right* 1: Drift 2: Some effort against gravity 3: No effort against gravity *Left* 4: No movement U: Untestable (joint fused or limb amputated) *(do not add score)*	
6.	**Motor function – Leg** 0: Normal (holds leg in 30^0 position for 5 seconds without drift) *Right* 1: Drift 2: Some effort against gravity 3: No effort against gravity *Left* 4: No movement U: Untestable (joint fused or limb amputated) *(do not add score)*	
7.	**Limb ataxia** (finger/nose, heel/shin testing) 0: No ataxia 1: Present in one limb 2: Present in two limbs U: Untestable (joint fused or limb amputated) *(do not add score)*	
8.	**Sensory** (use pinprick to test arms, legs, trunk & face – compare the sides) 0: Normal 1: Mild to moderate decrease in sensation 2: Severe or total sensory loss (including those in coma)	
9	**Best Language** (ask patient to describe picture, name items, read sentences) 0: No aphasia 1: Mild to moderate aphasia 2: Severe aphasia 3: Mute (including those in coma)	
10.	**Dysarthria** (ask patient to read several words) 0: Normal articulation 1: Mild to moderate slurring of words 2: Near unintelligible or unable to speak U: Untestable (intubated or other physical barrier to speech) *(do not add score)*	
11.	**Extinction & inattention** (formerly neglect) (use visual or sensory double stimulation) 0: Normal 1: Inattention or extinction to bilateral stimulation in one of the sensory modalities 2: Severe hemi-inattention or hemi-inattention to more than one modality	
	Total Score	

Any other stroke deficit not captured by NIHSS? Yes: ☐ No ☐

If **YES** Please specify: _____

7 . FUNCTIONAL STATUS BEFORE THIS STROKE

Did the patient require assistance from anyone to undertake activities of daily living (e.g. walking, showering, dressing, feeding, toileting)? Yes ☐ No ☐

8. FUNCTIONAL STATUS NOW

Able to lift both arms off the bed? Yes ☐ No ☐

Able to walk (even with a walking aid) but without the help of another person? Yes ☐ No ☐

9. PATIENT'S CURRENT MOOD (Patient Health Questionnaire-2)

Over the past 2 weeks, have you often been bothered by:

i. Little interest or pleasure in doing things? Yes ☐ No ☐ Unknown ☐

ii. Feeling down, depressed, or hopeless? Yes ☐ No ☐ Unknown ☐

10. TYPE OF STROKE

Does brain scan show recent intracerebral bleeding? Yes ☐ No ☐

If yes, is the bleeding likely to be due to haemorrhagic transformation of an infarct? Yes ☐ No ☐ (Go to Q11)

If Ischaemic, with/without haemorrhagic transformation, please complete Stroke Classification & Cause sections

If **Classification of ischaemic stroke (OCSP based on clinical and brain scan features)** *(please tick most appropriate)*

i. **T**otal **A**nterior **C**irculation **S**yndrome (TACS) ☐
ii. **P**artial **A**nterior **C**irculation **S**yndrome (PACS) ☐
iii. **LAC**unar **S**yndrome (LACS) ☐
iv. **Po**sterior **C**irculation **S**yndrome (POCS) ☐
v. Uncertain ☐

What is the most likely **cause of the Ischaemic stroke** *(please tick most likely)*

i. Large artery disease (cortical stroke (TACS/PACS +carotid atheroma >50% with no other cause)) ☐
ii. Small vessel disease (LACS without carotid atheroma or cardiac source) ☐
iii. Embolism from the heart (e.g. Atrial Fibrillation, prosthetic valve, endocarditis) ☐
iv. Another cause (e.g. dissection, illicit drugs) ☐
v. Unknown or uncertain cause (no cause identified or more than one of above) ☐

11. CONTACT DETAILS

PATIENT'S CONTACT DETAILS TO ALLOW CENTRAL FOLLOW UP

House no/ name: _____

Street name: _____

Town/City: _____ Postcode: _____

Tel No (home): _____ Tel No (work): _____ Tel No (mobile): _____

OTHER POSSIBLE CONTACTS

(Family members or close friends who may be contacted if we can't contact the patient.)

Name	**Relationship to patient**	**Tel Number(s)**: **(Home)**	**(Work)**	**(Mobile)**
1. _____	_____	_____/	_____/	_____
2. _____	_____	_____/	_____/	_____
3. _____	_____	_____/	_____/	_____

GENERAL PRACTITIONERS CONTACT DETAILS

GP name: _____

Practice name: _____

Street name: _____

Town/City: _____ Postcode: _____

Tel No: _____ Fax No (if available): _____

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12. RANDOMISATION

To randomise this patient log on to the FOCUS trial website:

www.focustrial.org.uk

You MUST record the patient id and allocated treatment numbers below

FOCUS trial patient ID number: ☐☐☐☐

Allocated Treatment No. ☐☐☐☐

The randomisation service will automatically generate an email/fax to your centre coordinator/administrator and pharmacist to ensure the allocated treatment is dispensed.

The randomisation service will also automatically generate a prescription for the patient

Please print the FOCUS prescription, make sure it has been signed by the prescriber & give it to your local pharmacist.

Please ensure that the patient is discharged WITH their supply of trial medication.

For assistance please call the FOCUS 24 hour help line on 0131 242 7741.

PLEASE FILE THE ORIGINAL COPY OF THIS RANDOMISATION FORM IN THE CRF SECTION OF YOUR SITE FILE AND A COPY IN THE PATIENT'S MEDICAL RECORDS.