Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Study Specific

Performing the Endometrial Scratch procedure in Women Undergoing First Time IN Vitro Fertilisation (IVF) when participating in the HTA funded Endometrial Scratch trial.

SOP Number	1	**Version Number**	1.1
Date effective	15/08/2016	**Author**	Clare Pye
Related SOPs			

Chief Investigator

Approved by (name & role)	Mostafa Metwally. Chief Investigator	**Date Finalised:**	15/08/2016
Signature		**Date Signed:**	15/08/2016

Standard Operating Procedure: Research Department

Performing the Endometrial Scratch procedure in Women Undergoing First Time IN Vitro Fertilisation (IVF) when participating in the HTA funded Endometrial Scratch trial.

This SOP will outline the how & when the Endometrial Scratch procedure will be performed for the Fertility units participating in the NIHR HTA funded Endometrial Scratch study.

Background

When patients are recruited to the NIHR HTA Project: 14/08/45 – ENDOMETRIAL SCRATCH Trial - A Multicentre Randomised Controlled Trial of Induced Endometrial Trauma In Women Undergoing First Time In Vitro Fertilisation (IVF) Portfolio ID: 30491, approximately 50% of the patients recruited to this study will be randomised to receive the Endometrial Scratch procedure which is currently being performed clinically for women having experienced several unsuccessful IVF cycles but has not yet being thoroughly tested in women who are having IVF for the first time. This SOP aims to document when, where and by whom this procedure should be performed.

Acronyms

ES	Endometrial Scratch
IVF	In Vitro Fertilisation
ICSI	Intracytoplasmic Sperm Injection
LH	luteinising hormone
ITT	Intention To Treat

Procedure

1. The local Principal Investigator and research team (to include: Research Nurse/Midwife, Research Officer/Administrator, Clinical nurse etc.) will be contacted by the patient randomised to receive the Endometrial Scratch (ES) procedure as part of their voluntary participation in the ES Trial when their menstrual cycle begins and arrange to have the ES procedure performed in the mid-luteal phase of that cycle as per the fertility units local protocols.

Antagonist protocol:

Women who are randomised to receive the Endometrial Scratch procedure will have the procedure performed in the mid-luteal phase of the menstrual cycle preceding the menstrual cycle where the IVF cycle is planned.
Women will contact the clinic when their menstrual cycle begins properly (i.e. proper bleeding starts) and depending on the length of the woman's cycle the ES procedure will be performed in the mid-luteal phase (i.e. approximately 5-7days before the expected next period) as per local protocol.

Note: The length of the woman's cycle should be taken into account when arranging the scratch procedure.

Long protocol:

For women undergoing the long protocol, those starting their downregulation on day 21 of the cycle can have their scratch performed around the same time +/- 2 days of that cycle.

Those starting downregulation on day 2 should have the scratch performed in the mid-luteal phase of the previous cycle in the same way as those having the antagonist protocol mentioned above.

2. Women who have consented to participate in the tissue sub-study at Sheffield & Southampton fertility units and randomised to receive the ES procedure will be supplied with an ovulation kit at their routine clinical appointment in which they consent to participate in the trial. The women will inform their Fertility Unit when the test is positive (LH surge has been detected). ES will be performed 7-9 days later.

3. Once an appointment time and date is confirmed, the research team will send a letter to the participant to confirm when the procedure will be undertaken. In all sites, women who fail to contact the fertility unit to arrange their Endometrial Scratch procedure will be contacted by the research team.

4. Where applicable, the participant will be required to use a barrier method of contraception in the cycle where the ES will be performed and this should be confirmed prior to the procedure being performed. If there is a chance of a natural conception but contraception has not been used prior to the procedure being received then the procedure should be delayed until the next cycle but this should be discussed with the patient and clinical team as it will result in a delay of the IVF treatment cycle. If the woman does not wish to delay her IVF treatment then she should continue with her IVF/ICSI as planned without receiving the ES procedure. A protocol violation form should be completed.

5. Women will be advised to take a suitable analgesic such as paracetamol or ibuprofen prior to the ES procedure for pain relief.

6. The procedure will be performed by either a Clinician or Nurse, with suitable skills & experience to perform the procedure. The cervix is first exposed with the help of a vaginal speculum. The cervix is then cleaned and a uterine sampler (Pipelle or similar) is introduced into the uterine cavity. The sampler's plunger is then withdrawn to create the negative pressure necessary for the procedure. The sampler is then gently moved in and out inside the uterine cavity 3-4 times while rotating to ensure that all aspects of the uterine cavity have been exposed to the procedure. The sampler is then removed and disposed of as per local procedure. For the Sheffield and Southampton sub study where the participant has consented to the storage of tissue, the tissue will be stored and transferred as per protocol and the sampler will then be disposed of.

7. Woman will be asked to complete a visual pain scale (likert) to assess their pain and tolerability assessment of the procedure within 30 minutes of the initial ES procedure, 24hrs later and then again seven days after the ES procedure. The Clinician/Nurse undertaking the procedure should ask the women to complete the visual pain scale directly after the procedure. Adverse events should also be collected (see adverse event SOP).

8. The Clinician/Nurse undertaking the procedure should enter data into the online database directly after the procedure is performed.

9. Routine IVF/ICSI commences

Appendix 1 SOP revisions and history

SOP number & version	Effective date	Reason for change	Author
THIS SOP			
Version 1.0 dated 21072016	21/07/2016	Performing the Endometrial Scratch procedure in Women Undergoing First Time IN Vitro Fertilisation (IVF) when participating in the HTA funded Endometrial Scratch trial.	Clare Pye
Version 1.1 dated 15082016	15/08/2016	Details added regarding timing of endometrial scratch in relation to the women's menstrual cycle	Clare Pye

SOP Training Log : Endometrial Scratch procedure

	Name of Staff	Job Title & Department	Training date	I confirm that I understand & agree to work to this SOP (signed)
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