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Endometrial scratch trial

Submission date
31/05/2016

Recruitment status
No longer recruiting

Registration date
31/05/2016

Overall study status
Completed

Last Edited
08/02/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
In order for a woman to become pregnant, the fertilized egg must attach (implant) itself to the lining of the womb. In vitro fertilization (IVF) is a technique used to help people with fertility problems to have a baby. During IVF, couples donate their own sperm and eggs (or use sperm and eggs from a donor). The egg is fertilized by the sperm outside of the body to create an embryo and then returned to the woman's womb to develop. Although IVF has become more and more successful in recent years, there is still a relatively high failure rate. Taking a small amount of tissue from the lining of the womb (endometrium) can sometimes improve the chance of achieving a pregnancy in women who have previously had several unsuccessful attempts at In Vitro Fertilisation (IVF). This procedure has been named "endometrial scratch" (ES). It is not known exactly why performing an Endometrial Scratch may be beneficial, but it is thought that the process of "scratching" the lining of the womb may release certain chemicals that are important in helping the fertilised egg (embryo) stick to the lining of the womb (implantation). The use of Endometrial Scratch has not yet been fully tried in women who are about to have IVF for the first time. If found to be beneficial then it could be used to improve the chance of achieving a pregnancy for a large group of women without the need for repeated IVF attempts. The aim of this study is to investigate the effectiveness of performing an Endometrial Scratch in younger women (37 years of age or younger) about to start their first IVF treatment cycle.

Who can participate?
Healthy women aged between 18 and 37 who are having their first cycle of IVF.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group undergo their IVF treatment in the usual way. Participants in the second group also undergo standard IVF, but attend an additional outpatient appointment in which the endometrial scratch is performed (around one week before their IVF treatment starts). Women are advised to take some simple painkillers beforehand (such as paracetamol) as these should lessen the chance of any discomfort as the procedure can sometimes cause period like cramps. The procedure involves placing a small tube (about the size of a small drinking straw) through the neck of the womb and then the lining of the uterus (the endometrium) is gently 'scratched'. Participants in both groups are followed up for around 10.5 months to see whether or not they get pregnant and have a healthy baby.

What are the possible benefits and risks of participating?
There are no known direct benefits of participating, although the endometrial scratch procedure could help increase the amount of live births. Performing the Endometrial Scratch has no clear risks although, in theory, inserting any instrument into the womb could carry a risk of infection. However all women having IVF are routinely screened for important vaginal infections before starting their IVF treatment.

Where is the study run from?
University of Sheffield Clinical Trials Research Unit (UK)

When is the study starting and how long is it expected to run for?
July 2016 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Robin Chatters
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Study website
http://www.sheffield.ac.uk/scratchtrial

Contact information

Type(s)
Public

Contact name
Mr Robin Chatters

Contact details
Clinical Trials Research Unit
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30491

Study information

Scientific Title
A multicentre randomised controlled trial of induced endometrial scratch in women undergoing first time in vitro fertilisation (IVF)

Study objectives
The aim of this study is to examine the effect of an Endometrial Scratch (ES) performed in the midluteal phase prior to a first time IVF/ICSI cycle, on the chances of achieving a clinical pregnancy and live birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Berkshire Research Ethics Committee, 23/03/2016, ref: 16/SC/0151

Study design
Randomised; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and sexual medicine; UKCRC code/ Disease: Reproduction/ Other obstetric conditions, not elsewhere classified

Interventions
Women will be randomised to either the intervention or control arm using an online system at a ratio of 1:1 using stratified block randomisation with variable blinded block sizes. Intervention participants will receive the endometrial scratch intervention (i.e. endometrial trauma) in the midluteal phase of their menstrual cycle, during the menstrual cycle preceding that in which they are due to have their IVF/ICSI treatment. Both arms will receive usual IVF/ICSI therapy. Women randomised to the control arm will not receive any intervention above normal care.

Intervention Type

Other

Primary outcome measure
Live birth rate (LBR) after completed 24 weeks gestation is determined by telephone contact with the participant 10.5 months post egg collection.

Secondary outcome measures
1. Acceptability of the Endometrial Scratch procedure is determined by telephone contact with the participant directly after, 24 hours and 7 days post procedure
2. Implantation rate based on a positive serum Beta hCG approximately day 14 post egg collection
3. Clinical pregnancy rate is measured at/after 8 weeks gestation
4. Miscarriage rate is measured 3 and 6 month post egg collection
5. Ectopic pregnancy rate is measured at/after 8 weeks gestation
6. Multiple birth rate is measured 10.5 months post egg collection
7. Preterm delivery rate is measured 6 and 10.5 months post egg collection
8. Still birth rate is measured 6 and 10.5 months post egg collection
9. Adverse events are measured post intervention, 2 weeks, 3- 6- and 10.5 months post egg collection
10. Resource use is measured at baseline, 3 and 10.5 months post egg collection
11. Patient costs are measured 3 months post egg collection

Overall study start date
01/12/2016

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Women aged ≥ 18 and ≤ 37 years of age at time of oocyte removal
2. Women expected to receive IVF with or without ICSI treatment using the antagonist or long protocol only
3. First time IVF with or without ICSI treatment
4. Ovulatory menstrual cycle. (Regular menstrual cycles with ovulatory levels of midluteal serum progesterone as defined by local laboratory protocols)
5. Normal uterine cavity assessed by transvaginal sonography at screening and no endometrial abnormalities such as , polyps, suspected intrauterine adhesions, uterine septa, submucosal fibroids or intramural fibroids exceeding 4 cm in diameter as assessed by the investigator that would require treatment to facilitate pregnancy
6. Local procedures have been followed to exclude relevant vaginal/uterine infections prior to starting treatment
7. Expected good ovarian reserve as assessed clinically and or laboratory (normal early follicular FSH (<10) & normal AMH) and no history of previous radiotherapy or chemotherapy
8. Expected good responders in whom blastocyst transfer is expected (as assessed by clinical judgement)
9. Understands/willing to comply with the protocol
10. Willing to use a condom if randomised to Endometrial Scratch (ES) in the cycle where the ES procedure is performed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 1044; UK Sample Size: 1044

Total final enrolment
1048

Key exclusion criteria
1. Single embryo transfer is not anticipated
2. Previous trauma/surgery to the endometrium e.g. resection of submucous fibroid, intrauterine adhesions
3. BMI≥ 35 kg/m2
4. Known Grade 4 (severe) endometriosis
5. Women who have received cycle programming through the use of progestogens or the contraceptive pill in the lead up to their IVF treatment and for whom a wash out period of one month will not be possible
6. Currently participating in any other fertility study or a study involving medical/surgical intervention or previously randomised into this trial

Date of first enrolment
01/07/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Clinical Trials Research Unit
ScHARR
Regent Court
30 Regent Street

Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Northern General Hospital
Herries Road
Sheffield
England
United Kingdom
S5 7AU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/05/2018	17/05/2019	Yes	No
Results article		18/06/2021	01/06/2021	Yes	No
Results article	Qualitative results	16/09/2021	21/09/2021	Yes	No
Results article		01/01/2022	08/02/2022	Yes	No
HRA research summary			28/06/2023	No	No