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Pre In vitro fertilisation (IVF) pipelle biopsy following a previous unsuccessful IVF cycle

Submission date
26/04/2012

Recruitment status
No longer recruiting

Registration date
07/06/2012

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary
Background and study aims
Management of implantation failure (i.e. attaching of the embryo to the lining of the womb) despite transfer of good quality embryos remains challenging in IVF clinics. Recent studies suggests that the outcome of the in vitro fertilisation (IVF) treatment can be improved if a gentle scratching is done to the lining of the womb before the treatment cycle.
We propose a gentle scratching to the lining of the womb in the cycle before the IVF cycle by a simple outpatient procedure to see if it improves the pregnancy rates.

Who can participate?
Women between 23-37 years of age undergoing an IVF cycle with a history of one or more previous unsuccessful IVF cycles despite having good quality embryos transfered.

What does the study involve?
Local scratching of the endometrium (lining of the womb) of 64 patients in the cycle before the IVF treatment cycle, who were selected by computer generated randomised numbers from a total of 128 patients. The gentle scratching (biopsy) is to be performed on Day 21 of the cycle preceding IVF, after informed consent. The other 64 patients with no intervention will serve as controls. The biopsy is done using a pipelle sampler which is a flexible transparent polypropylene sheath. The procedure requires no local anesthesia or cervical dilatation.

What is the possible benefits and risks of participating?
There are no added disadvantages and risks over and above the routine IVF treatment. The pipelle biopsy sampler is an extremely safe outpatient procedure, however, some women experience light period pain during the sampling and maybe some discharge after the procedure. We cannot promise the study will help you but the information we get from this study will help improve the treatment of people with IVF failure despite the transfer of good quality embryos.

Where is the study run from?
Homerten Fertility Centre, Homerton University Hospital, London, UK

When is the study starting?
May 2012. The study is expected to run for six months.

Who is funding the study?
Homerton Fertility Centre.

Who is the main contact?
Dr G Srivastava
garima.srivastava@homerton.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Garima Srivastava

Contact details
Fertility Unit
Homerton University Hospital
London
United Kingdom
E9 6SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled study of pre IVF pipelle biopsy of the endometrium in women with previous unsuccessful IVF treatment

Study hypothesis
Does the gentle scratching to the lining of the womb in the cycle preceding IVF result in a higher clinical pregnancy rate (a fetal heart beat seen on ultrasound examination) in the subsequent IVF treatment cycle?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Harrow, 16/03/2012

Study design
Single centre randomised controlled trial

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

Condition
Subfertility

Interventions
Intervention group: Local scratching of the endometrium (lining of the womb) of 64 patients in the cycle before the IVF treatment cycle. The biopsy is to be performed on Day 21 of the cycle preceding IVF, after informed consent. It is done by a pipelle sampler which is a flexible transparent polypropylene sheath. The procedure requires no local anesthesia or cervical dilatation.

Control group - No intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical pregnancy rate

Secondary outcome measures
Implantation rate (number of embryos transferred divided by number of pregnancies)

Overall study start date
25/04/2012

Overall study end date
25/10/2012

Eligibility

Participant inclusion criteria
1. Between 23- 37 years of age
2. At least one previous unsuccessful IVF cycle
3. At least one good quality embryo transferred in the previous unsuccessful cycle

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
128

Participant exclusion criteria
1. Age less than 23 and more than 37 years
2. Previous poor quality embryos

Recruitment start date
25/04/2012

Recruitment end date
25/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Fertility Unit
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Homerton University Hospital

Sponsor details
c/o Mr Roger Griffith
Research and Development Department
London
England
United Kingdom
E9 6SR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00x444s43

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton University Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration