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Effect of endometrial scratch on repeat implantation failure following in vitro fertilization embryo transfer or frozen embryo transfer

Submission date
16/01/2013

Recruitment status
No longer recruiting

Registration date
19/02/2013

Overall study status
Completed

Last Edited
19/02/2013

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Although the results of in vitro fertilization-embryo transfer (IVF-ET) have been steadily increasing over recent years, it still means that approximately 6 out of 10 of women are unable to successfully conceive with each treatment cycle. It also follows that approximately 2 out of 10 women will fail to conceive after two or three IVF attempts. Recurrent implantation failure (RIF) is a most distress situation. Several studies (the number of cases included was quite small) reported that endometrial scratch is of benefit to improve the pregnancy outcome of women with RIF. A recent analysis of data has shown that large studies are required before endometrial scratch or injury can be warranted in routine clinical practice. Hence, we wish to conduct such a study to evaluate if endometrial scratch does have impact on the IVF treatment outcome in women with two or more embryo transfer failures.

Who can participate?
Patients with repeated implantation failure (two or more) undergoing in vitro fertilization embryo transfer (IVF-ET) or frozen embryo transfer (FET), patients aged no more than 40 years old with basal follicle-stimulating hormone (FSH)<10IU/L and without history of uterine cavity operation in two months.

What does the study involve?
Patients fulfilling the inclusion criteria will be randomly allocated to two groups
Group 1, endometrial scratch was offered on day of observation of Luteinizing hormone (LH) + 7 immediately prior to commencement of IVF treatment
Group 2, no endometrial scratch was performed.

What are the possible benefits and risks of participating?
Endometrial scratch might improve the potential of embryo implantation. The side effect is associated with injury to the endometrium, such as bleeding, pain and infection, however, there are no reports related to the risks mentioned above.

Where is the study run from?
Reproductive medical center of Sir Run Run Shaw hospital, medical school, Zhejiang university, China.

When is the study starting and how long is it expected to run for?
The study was started on January 1, 2013 and will run for 2 years or until 800 patients were included.

Who is funding the study?
National Natural Science Foundation of China.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Effect of endometrial scratch on repeat implantation failure following in vitro fertilization embryo transfer or frozen embryo transfer: a randomized controlled study

Study objectives
Patients with repeated implantation failure (RIF) have a higher implantation rate and pregnancy rate following in vitro fertilization embryo transfer (IVF-ET) or frozen embryo transfer (FET) after undergoing endometrial scratch compared with patients without endometrial scratch.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Assisted Reproduction Unit, Department of Obstetrics and Gynecology, Sir Run Run Shaw Hospital, College of Medicine, Zhejiang University,Hangzhou, China, 15 January 2013

Primary study design
Interventional

Study design
Prospective randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infertility

Interventions
Endometrium scratching in seventh day after observation of Luteinizing hormone (LH) surge prior to an IVF or frozen embryo transfer (FET) cycle in study group. No extra administration prior to an IVF or FET cycle in control group.

Control group: patients with RIF without endometrial scratch before IVF-ET or FET.

Study group: patients with RIF undergoing endometrial scratch before IVF-ET or FET.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Implantation rate
2. Clinical pregnancy rate defined as the presence of a fetal sac by ultrasound scanning

Key secondary outcome(s)
1. Endometrial thickness
2. Endometrial type

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Patients with repeated implantation failure (two or more) undergoing in vitro fertilization embryo transfer (IVF-ET) or frozen embryo transfer (FET)
2. Patients aged no more than 40 years old

3. Patients with basal follicle-stimulating hormone (FSH)<10IU/L
4. Patients without history of uterine cavity operation in two months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with hydrosalpinx
2. Patients with polycystic ovary syndrome (PCOS)
3. Patients with history of endometrium adhesion
4. Patients with uterine malformation; uterine fibroid
5. Patients with acute genital tract inflammation
6. Patients with history of using hormone such as oral contraceptive in one month

Date of first enrolment
16/01/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
China

Study participating centre
Assisted Reproduction Unit
Hangzhou
China
310016

Sponsor information

Organisation
Zhejiang University (China)

ROR
https://ror.org/00a2xv884

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Zhejiang University (China) - Assisted Reproduction Unit, Department of Obstetrics and Gynecology, Sir Run Run Shaw Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration