

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	<input type="checkbox"/> Prospectively registered
Registration date 19/02/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2013	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Prospective randomized controlled study

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

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 measure

1. Implantation rate
2. Clinical pregnancy rate defined as the presence of a fetal sac by ultrasound scanning

Secondary outcome measures

1. Endometrial thickness
2. Endometrial type

Overall study start date

16/01/2013

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

Age group

Adult

Sex

Female

Target number of participants

800

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)

Sponsor details

c/o Songying Zhang

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Sponsor type

Hospital/treatment centre

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

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