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

Submission date	Recruitment status	Prospectively registered
11/01/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/04/2012	Completed	Results
Last Edited	Condition category	Individual participant data
12/04/2012	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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 injury 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 injury compared with patients without endometrial injury.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Peking University Third Hospital Ethics Committee, Beijing, China, 01 November 2011 ref: Shengzhi010

Study design

Prospective randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

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 fifth day after ovulation prior to an IVF or 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 injury before IVF-ET or FET. Study group: patients with RIF undergoing endometrial injury before IVF-ET or FET.

Intervention Type

Other

Phase

Not Specified

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
- 3. Blood flow under endometrium

Overall study start date

05/11/2011

Completion date

31/12/2012

Eligibility

Key inclusion criteria

- 1. Patients with repeated implantation failure (three or more) undergoing in vitro fertilization embryo transfer (IVF-ET) or frozen embryo transfer (FET)
- 2. Patients with normal preoperative routine checks
- 3. Patients aged 40 years old or younger with basal follicle-stimulating hormone (FSH)<10IU/L and numbers of follicles>5 in hibateral ovaries
- 4. Patients without history of uterine cavity operation in two months

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

400

Key exclusion criteria

- 1. Patients with hydrosalpinx
- 2. Patients with history of endometrium adhesion
- 3. Patients with uterine malformation
- 4. Patients with acute genital tract inflammation
- 5. Patients with history of using hormone such as oral contraceptive in three months

Date of first enrolment

05/11/2011

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

China

Study participating centre
Reproductive Medical Center

Beijing China 100191

Sponsor information

Organisation

Peking University Third Hospital (China)

Sponsor details

48, Huayuan Bei Road Haidian District Beijing China 100191

Sponsor type

Hospital/treatment centre

Website

http://www.at0086.com/PUTH/

ROR

https://ror.org/04wwqze12

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Peking University Third Hospital, Beijing (China)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration