

Endometrial injury prior to first cycle IVF/ICSI

Submission date 04/06/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/06/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 08/06/2015	Condition category Pregnancy and Childbirth	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

It is possible that scratching the inside of the womb lining before in vitro fertilisation (IVF) could increase pregnancy rates. However, recent studies have not provided sufficient information in order to conclude that this is the case. The aim of this study is to find out if scratching of the womb lining increases the likelihood of pregnancy after the IVF or intra-cytoplasmic sperm injection (ICSI) treatment.

Who can participate?

Patients undergoing first cycle IVF / ICSI.

What does the study involve?

The patients are randomly allocated to one of two groups. Those in group 1 (intervention group) have the inside of their womb scratched before being given their fertility treatment. Those in group 2 (control) do not have the inside of their womb scratched before treatment.

What are the possible benefits and risks of participating?

There is the possible benefit of improving the chance of getting pregnant after IVF. There is a minimal risk of pain or vaginal bleeding during or after the procedure.

Where is the study run from?

Minia Infertility Research Unit and Minia IVF Unit, Minia, Egypt

When is study starting and how long is it expected to run for?

June 2012 to September 2013.

Who is funding the study?

Obstetrics and Gynecology department, Faculty of Medicine, Minia University (Egypt)

Who is the main contact?

Dr Ahmad Mahran
ezzeldin_ahmad@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Ahmad Mahran

Contact details
Department of Obstetrics and Gynecology
Faculty of Medicine
Minia University
Minia
Egypt
61111
00201115551073
ezzeldin_ahmad@yahoo.com

Additional identifiers

Protocol serial number
153052012

Study information

Scientific Title
The effect of endometrial injury on first cycle IVF/ICSI outcome: a randomized controlled trial.

Study objectives
Endometrial injury performed in the luteal phase of the cycle preceding to IVF/ ICSI improves clinical pregnancy and live birth rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Faculty of Medicine, Minia University, Egypt, 02/05/2012

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Outcome of IVF / ICSI cycles.

Interventions
Endometrial scratch performed in the cycle preceding the IVF/ICSI cycle

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Live birth rate; calculated as the ration of number of patients with live births divided by the number of patients who had embryo transfer
2. Implantation rate; calculated as number of gestational sacs evident by ultrasound divided by the number of transferred embryos

Key secondary outcome(s)

1. Clinical pregnancy rate; calculated as the number of patients with clinical pregnancy divided by the number of patients who had embryo transfer
2. Miscarriage rate per clinical pregnancy; calculated as the number of patients who had miscarriage divided by the number of patients who had clinical pregnancies
3. Multiple gestations rate; calculated as the number of patients who had multiple gestation divided by the number of patients who had clinical pregnancies
4. Pain; reported pain during the intervention
5. Bleeding; reports of abnormal bleeding during or after the intervention

Completion date

01/09/2014

Eligibility

Key inclusion criteria

1. Age between 20-40 years
2. FSH $\leq$ 12
3. Normal uterine cavity by hysteroscopy (done routinely for all cases prior to ICSI)
4. $\geq$ 2 good quality embryos replaced

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Age > 40 years
2. Abnormal uterine cavity due to submucous fibroid, endometrial polyps, Asherman's syndrome or congenital uterine malformations
3. Patients who have < 2 good quality embryos at time of transfer were excluded from the analysis

Date of first enrolment

01/06/2012

Date of final enrolment

01/09/2013

Locations

Countries of recruitment

Egypt

Study participating centre**Minia infertility research unit**

Minia

Egypt

61111

Study participating centre**Minia IVF unit**

Minia

Egypt

61111

Sponsor information

Organisation

Department of Obstetrics and Gynecology

ROR

<https://ror.org/02hcv4z63>

Funder(s)

Funder type

University/education

Funder Name

Department of Obstetrics and Gynecology, Faculty of Medicine, Minia University, Minia, Egypt

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request