

# Endometrial injury prior to first cycle IVF/ICSI

<b>Submission date</b> 04/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/06/2015	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Ahmad Mahran

**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Study design**

Randomized 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 contact details to request a participant information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2012

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

400

**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

**Sponsor details**

Faculty of Medicine

Minia University

Minia

Egypt

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**Sponsor type**

University/education

**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****Publication and dissemination plan****Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request