# Endometrial injury prior to first cycle IVF/ICSI

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

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## 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

## Study design

Randomized controlled trial

## Primary study design

Interventional

### 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 ≤ 12
- 3. Normal uterine cavity by hysteroscopy (done routinely for all cases prior to ICSI)
- 4. ≥ 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

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes