

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Fertility outcome after operative laparoscopy versus no treatment in infertile women with minimal or mild endometriosis

#### Protocol summary

##### Summary

The objective of this study was to evaluate the effect of laparoscopic surgical treatment on clinical pregnancy in infertile women with minimal or mild endometriosis. This clinical trial study was performed in 146 infertile women (20-35 years old) who were referred to the gynecological clinic between April 2008 and March 2009. After considering inclusion and exclusion criteria and confirmation of minimal or mild endometriosis by diagnostic laparoscopy in all patients, they were randomly assigned into two groups using consecutively numbered, opaque sealed envelopes. Diagnostic laparoscopy (no treatment) was performed for the first group but the second group underwent operative laparoscopy as well. The primary outcome of the present study was normal intrauterine pregnancy occurrence during 9 months of follow-up. If  $\beta$ -HCG was positive sonography would be performed for confirmation of normal intrauterine pregnancy. Secondary outcome was complications during or after operation such as: intestinal injury, slight tear of the tubal serosa, vascular trauma, infection of wounds and hematomas and finally urinary tract infection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012311952N2**

Registration date: **2011-12-08, 1390/09/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-12-08, 1390/09/17

##### Registrant information

##### Name

Ashraf Moini

##### Name of organization / entity

Tehran University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 3283

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hosp\_arash@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2008-01-01, 1386/10/11

##### Expected recruitment end date

2010-01-01, 1388/10/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Fertility outcome after operative laparoscopy versus no treatment in infertile women with minimal or mild endometriosis

##### Public title

Comparison of laparoscopic surgery with no treatment in infertile women with endometriosis

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

Inclusion criteria: age between 20–35 years old, unexplained infertility more than 1 year, normal semen analysis, normal ovulatory cycles (menstrual interval 24-35 days and biphasic basal temperature), normal

hormonal assay (TSH, FSH, PRL) and normal hysterosalpingography. Exclusion criteria: surgical history for infertility or endometriosis, oophorectomy, salpingectomy, history of PID (Pelvic Inflammation Disease) and women who received any treatment for endometriosis during the previous 3 months.

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **76**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences

**City**

Tehran

**Postal code****Approval date**

2011-11-28, 1390/09/07

**Ethics committee reference number**

90/130/1587/3

**Health conditions studied****1****Description of health condition studied**

Pregnancy, childbirth and the puerperium

**ICD-10 code**

028-9

**ICD-10 code description**

Abnormal finding on antenatal screening of mother, unspecified

**Primary outcomes****1****Description**

normal intrauterine pregnancy occurrence

**Timepoint**

Every 8 weeks during 9 months follow-up.

**Method of measurement**

$\beta$ -HCG test; and If  $\beta$ -HCG was positive, sonography will be performed for confirmation of normal intrauterine pregnancy. (Clinical pregnancy was defined by the visualization of an embryo with cardiac activity at 6-7 weeks of pregnancy)

**Secondary outcomes****1****Description**

complications during or post operation such as: intestinal contusion, slight tear of the tubal serosa, vascular trauma, infection of wounds and hematomas and finally urinary tract infection.

**Timepoint**

during or post operation

**Method of measurement**

Clinical examination and observation

**Intervention groups****1****Description**

Control group: diagnostic laparoscopy (no treatment after diagnosis)

**Category**

Treatment - Surgery

**2****Description**

Intervention group: diagnostic laparoscopy as well as appropriate operative laparoscopy

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Arash Hospital

**Full name of responsible person****Street address****City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Dr Akbar Fotouhi

**Full name of responsible person**

Vice chancellor for research

**Street address**

Unit 601, Sixth floor, Keshavrz Blvd., Ghods Ave.,  
Tehran University of Medical Sciences

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Dr Akbar Fotouhi

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Ashraf Moini

**Position**

Associate Professor/MD

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## Person responsible for scientific

## inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Bitra Eslami

**Position**

MPH

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*