

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison effect of endometrial abrasion on the success of intrauterine sperm injection in both follicular and luteal phases in infertile women with unexplained infertility

#### Protocol summary

##### Study aim

Comparison effect of endometrial abrasion on the success of intrauterine sperm injection in two phases of follicular and luteal in infertile women with unexplained infertility

##### Design

This is a double blind, phase 3 randomized control clinical trial study that done on 75 women with infertility for unexplained reasons. Patients are distributed in three groups of 25 people using Random Allocation Software.

##### Settings and conduct

This double blind clinical trial study will be done in 2020-2021 in Shahid Beheshti Hospital in Isfahan. The study is double blind and patients were unaware of the endometrial abrasion phase. Also, the person evaluating the fertility outcome is unaware of the endometrial abrasion step.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age range of participants 38-21 years old; body mass index 29.9-18.5 kg / m<sup>2</sup>; normal hormonal tests (FSH less than 10 mIU / ml on days 2-3); normal thyroid status; bilateral tubal opening Follows in HSG or laparoscopy. Exclusion criteria: presence of adnexal mass in transvaginal ultrasound; normal fluid analysis of semen with a volume of 2-5 ml with a concentration of more than 20 million / ml; total motility greater than 50% and normal form more than 30%; spousal infections severe infertility; stage 3 and 4 endometriosis; infertility caused by defects in the fallopian tubes; levels of thyroid-stimulating hormone greater than 10 mL / ml; abnormal levels of thyroid hormone or prolactin; uterine fibroids or severe systemic or infectious disease.

##### Intervention groups

The intervention in this study on patients is endometrial abrasion, which is performed either in the follicular phase or in the luteal phase. Endometrial abrasion control is not

performed. All patients are treated with intrauterine sperm injection.

##### Main outcome variables

Fertility success

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130311012782N48**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **prospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

##### Registration date

2020-06-15, 1399/03/26

##### Registrant information

##### Name

Ali Mehrabi kushki

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-09-21, 1400/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison effect of endometrial abrasion on the success of intrauterine sperm injection in both follicular and luteal phases in infertile women with unexplained infertility

**Public title**

The effect of endometrial abrasion in both follicular and luteal stages on fertility success by intrauterine sperm injection

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Range age between 21-38 years old Body Mass Index between 18.5-29.9 kg/m<sup>2</sup> Levels of thyroid stimulating hormone less than 10 meq/ml in 2 to 3 days Normal thyroid condition Bilateral opening of fallopian tubes in HSG or laparoscopy

**Exclusion criteria:**

Existence of adnexal mass in transvaginal ultrasound Normal analysis of Semen liquid with a volume of 2-5 ml with a concentration of more than 20 million / ml Total sperm motility more than 50% Natural sperm form more than 30% husband with severe infertility Stages 3 and 4 endometriosis Infertility due to defects in the fallopian tubes Abnormal thyroid hormone or prolactin levels Uterine fibroids or severe systemic or infectious disease

**Age**

From **21 years** old to **38 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients with entry criteria are divided into three groups using Random Allocation Software. In this way, first the total sample size is entered into the software and then the number of groups is determined. Software output includes a list that randomly distributed sample size (75 people) in three groups A, B, and C. Patients are distributed in three groups according to the list, according to the time of referral, so that the sample size reaches the required number.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is double blind clinical trial study. Patients and outcome assessors are unaware of the type of intervention received. Endometrial abrasion was performed by the researcher without informing the patient in the follicular or luteal phase, but the outcome of the pregnancy was checked by a gynecologist who was not awareness about this.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Shahid Beheshti hospital, Motahari street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8434193474

**Approval date**

2020-01-03, 1398/10/13

**Ethics committee reference number**

IR.MUI.MED.REC.1398.013

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

Unexplained infertility

**ICD-10 code**

N97.9

**ICD-10 code description**

Female infertility, unspecified

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

Fertility success

**Timepoint**

6 months after intervention

**Method of measurement**

Measurement of beta HCG and vaginal ultrasonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Uterine abrasion between days 19 and 24 of the menstrual cycle before intrauterine injection of sperm and in the luteal phase

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group 2: Uterine endometrial abrasion on day 8 of the menstrual cycle and in the follicular phase before intrauterine injection of sperm

#### Category

Treatment - Surgery

### 3

#### Description

Control group: no uterine endometrial abrasion in 3 menstrual cycles and only Intrauterian Sperm Injection

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti hospital

##### Full name of responsible person

Mina Ghaed Amini

##### Street address

Shahid Beheshti hospital, Motahari street, Isfahan, Iran

##### City

Isfahan

##### Province

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##### Postal code

8434193474

##### Phone

+98 31 3236 7001

##### Email

ghaedamini@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjoo

#### Street address

Research faculty, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

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sh\_haghjoo@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Mina Ghaed Amini

##### Position

Resident of gynecology

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Shahid Beheshti hospital, Motahari street, Isfahan, Iran

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Isfahan

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham Naghshineh

**Position**

Isfahan

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Mehrabi

**Position**

Statistical Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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**Email**

al.mehrabi@gmail.com

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The project belongs to a government agency and cannot be shared.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available