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 / m2; 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

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Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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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/m2 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
Isfehan
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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Full name of responsible person
Mina Ghaed Amini
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Resident of gynecology
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Person responsible for updating data

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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