

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of endometrial Scratching on pregnancy outcome after intrauterine insemination (IUI) in patients with previous IUI failure, a randomized clinical trial

Protocol summary

Study aim

Investigating the effect of endometrial scratching in improving the results of intrauterine sperm injection (IUI) in patients with repeated IUI failure

Design

A clinical trial with a control group, randomized, single-blind will be performed on 192 patients. The random sequence will be prepared using the website www.sealedenvelope.com software.

Settings and conduct

The number of 192 patients who are referred to the infertility clinic of Akbar Abadi Hospital with a history of at least two failed IUIs were randomly divided into two intervention groups (endometrial scratching) and control group. Patients then undergo IUI. Finally, intrauterine pregnancy and live birth rates are compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women with unspecified or male infertility aged between 20-42 years who have previously had at least two failed IUIs; Exclusion criteria: severe endometriosis, severe male factor infertility, underlying metabolic diseases

Intervention groups

Intervention group: patients who undergo endometrial scratching. Control group: patients without endometrial scratching undergo vaginal examination simulating scratching.

Main outcome variables

Intrauterine pregnancy Live birth rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200421047152N2**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Arash Mohazzab

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2351 9630

Email address

amohazzab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of endometrial Scratching on pregnancy outcome after intrauterine insemination (IUI) in patients with previous IUI failure, a randomized clinical trial

Public title

Effect of endometrial Scratching on pregnancy outcome after intrauterine insemination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-42 year Unexplained infertility or mild male factor infertility Failure of at least two previous intrauterine insemination (IUI) cycles

Exclusion criteria:

Presence of endometriosis in stage 3 and 4 diagnosed by ultrasound Sever male factor infertility Underlying metabolic disease (hyperprolactinemia, thyroid disorder or any known metabolic disease) Ovarian follicle-stimulating hormone (FSH) level > 12 Body mass measurement > 30

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization will be done according to age (above and below 35 years) and using permuted blocks with a size of 4. The random list is generated by the website www.sealedenvelope.com software and will be given to an independent third party for concealment and will be revealed to the researcher respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be aware of being in a study with two groups, with and without endometrial scraping, but will not know whether endometrial scraping is being performed for them. To reach this goal patients in the control group will undergo a vaginal examination with a speculum and a cervical scraper will enter into the posterior fornix without scratching. Patients in the control group will not be informed about the intervention type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IUMS Biomedical Research Ethics Committee

Street address

Next to Milad Tower ,Hemat Highway

City

Tehran

Province

Tehran

Postal code

1134845764

Approval date

2023-01-11, 1401/10/21

Ethics committee reference number

IR.IUMS.REC.1401.833

Health conditions studied

1

Description of health condition studied

Infertility needs intrauterine insemination (IUI)

ICD-10 code

Z31.1

ICD-10 code description

Artificial insemination

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

5-6 weeks after IUI

Method of measurement

Transvaginal sonography

Secondary outcomes

1

Description

Live birth rate

Timepoint

28 weeks of pregnancy

Method of measurement

Phone based interview

2

Description

Chemical pregnancy rate

Timepoint

14 days after IUI

Method of measurement

Measurement of beta human chorionic gonadotropin serum level (Beta HCG)

Intervention groups

1

Description

Endometrial scratching intervention group: Endometrial scratching is done in the intrauterine sperm injection (IUI) cycle on day 5 or 6 from the beginning of the menstrual cycle. To perform endometrial scratching, the patient is placed in a lithotomy position. Then, the speculum is slowly placed in the vagina to expose the cervix, and with the use of a flexible catheter, the endometrium is scratched in a circular position after performing aspiration. The circular movement of the catheter starts and ends in 12 o'clock position, and then the catheter is removed. If the catheter does not pass through the tenaculum, the anterior edge of the cervix is used to grasp the. According to the level of Anti-Müllerian Hormone (AMH) and Ovarian Reserve Count (AFC), letrozole, Cinnal F, or Menstrual Gonadotropin (HMG) is used to stimulate the ovaries, depending on the initial response to stimulation. After starting the drugs, the follicle size is monitored. When the size of the follicles is greater than or equal to 18, two ampoules of human chorionic gonadotropin (HCG) are prescribed to release the egg, and the patient undergoes IUI after 36 hours.

Category

Treatment - Surgery

2

Description

Control group: Patients in this group will undergo a vaginal examination with a speculum and a cervical scraper will enter into the posterior fornix without scratching. According to the level of Anti-Müllerian Hormone (AMH) and Ovarian Reserve Count (AFC), letrozole, Cinnal F, or Menstrual Gonadotropin (HMG) is used to stimulate the ovaries, depending on the initial response to stimulation. After starting the drugs, the follicle size is monitored. When the size of the follicles is greater than or equal to 18, two ampoules of human chorionic gonadotropin (HCG) are prescribed to release the egg, and the patient undergoes IUI after 36 hours.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Mahnaz Ashrafi

Street address

Bagh-ferdous station, Molavi street

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Tehran

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1168743514

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

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Email

Keyvanlab@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Behnaz Mohabatian

Position

Infertility fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Ashrafi

Position

Professor in infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Arash Mohazzab

Position

Ph.D candidate

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

There is no further information.

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