

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The Effect of endometrial scratch on pregnancy rate in intra uterine insemination cycle(IUI).

Protocol summary

Study aim

Evaluation of pregnancy rate using endometrial scratch on the third day of the cycle in an infertile couple of intrauterine insemination (IUI)candidate.

Design

A randomized clinical trial study was randomly divided into two parallel groups by block randomization with a sample size of 60 in two groups of intervention and control (B, A). Random sequences based on random blocks of size 4 are recorded on a card and the cards in the envelope are arranged in order respectively.

Settings and conduct

A randomized clinical trial conducted on infertile female candidates for IUI in Valiasr Infertility Center that Randomly divided by block method into two intervention groups (endometrial scratch) and control (without an endometrial scratch).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: primary or secondary female infertility, Age(21-35), BMI(18-30), Normal hormonal Profile(FSH less than 10), Normal Thyroid, Open tubal and regular ovulation. Exclusion criteria: Sever male infertility, 3 or 4 stage of endometriosis, Tubal infertility, Abnormal Thyroid, Abnormal Prolactin, Fibroma, Systemic disease.

Intervention groups

Stimulation of ovulation with the one a day the Letrozole tab will be done the 3-7 day of menstrual cycle. when the diameters of 1-2 follicles reached more than 18 Millimeter, Human Chorionic Gonadotropin (HCG) is injected and 36-38 hours after IUI will be done. In the intervention group, in addition to the routine method, it is explained, On the 3rd cycle, by using catheter number 4, an endometrial scrub is performed. Patients undergo lithotomy and without anesthesia, an endometrial scratch on the posterior wall of the endometrium is injected by an infertility specialist. Control group: The routine procedure that described, is performed and endometrial scratch are not performed in this group.

Main outcome variables

Chemical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180624040214N1**

Registration date: **2018-11-21, 1397/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-21, 1397/08/30**

Update count: **0**

Registration date

2018-11-21, 1397/08/30

Registrant information

Name

Mina Jafarabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6658 1616

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jafarabadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of endometrial scratch on pregnancy rate in intra uterine insemination cycle(IUI).

Public title

Endometrial scratch on the incidence of pregnancy in intrauterine insemination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

secondary or primary female infertility Unknown infertility Age(21-35) BMI(18-30) Normal hormonal profile(FSH lower than 10) Normal Thyroid Open uterine tubal Regular ovulation

Exclusion criteria:

Sever male infertility 3 or 4 stage of endometriosis Tubal infertility FSH>10 m IU/ML Adenexal mass Abnormal Thyroid Abnormal Prolactin Fibroma Systemic disease

Age

From **21 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is using random blocks of size 4. Based on random blocks with the size 4, the first sample A-second A-third B-fourth B and so on continued until 120 samples were completed. A random sequence is performed using a number of sealed non-transparent envelopes, which randomly stores the random sequences onto the card, The cards in the envelope are placed in sequence respectively. The clinician examines patients in terms of entry and exit criteria, and the clinic's midwife allocates participants to the study groups randomly by randomization method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

6th floor, Ghods St, Keshavarz Blvd. Central Organization of the University, Deputy of Research and Technology of Tehran University of Medical Sciences .

City

Tehran

Province

Tehran

Postal code

14415

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.TUMS.VCR.REC.1397.533

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

Primary outcomes

1

Description

Chemical pregnancy rate

Timepoint

Fifteen days after intra uterine insemination.

Method of measurement

Blood test of B-HCG

Secondary outcomes

1

Description

Abortion rate

Timepoint

Two months after the positive of pregnancy test

Method of measurement

Vaginal sonography

2

Description

Ectopic pregnancy

Timepoint

Two weeks after a positive pregnancy test

Method of measurement

Intervention groups

1

Description

Intervention group: Stimulation of ovulation with Letrozole will be done the 3-7 day when the diameters of 1-2 follicles reached more than 18 millimeters, HCG is injected and after 36-38 hours, IUI will be done. In the intervention group , in addition to the routine method, On the 3rd cycle, by using Karman cannula 4, an endometrial scrub performed. Patients undergo lithotomy and without anesthesia, an endometrial scratch on the posterior wall of the endometrium is injected by an infertility specialist.

Category

Treatment - Surgery

2

Description

Control group: Stimulation of ovulation with Letrozole will be done the 3-7 day when the diameters of 1-2 follicles reached more than 18 millimeters, HCG is injected and 36-38 hours after IUI will be done, But endometrial scratch is not performed in this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Infertility Clinic Of Imam Khomeini Hospital

Full name of responsible person

Mina Jafarabadi

Street address

Infertility Clinic, 1st floor, No. 2, Vali-e-Asr Building, Imam Khomeini Hospital, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr .Zahra Ebrahimi

Position

Medical doctor

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

Medical Doctor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person

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Master

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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

keep up the secrets of the patients.

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available