

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of Endometrial biopsy in increasing pregnancy rates in infertile women under intra uterin insemination treatment

Protocol summary

Study aim

In this study, the effect of endometrial biopsy on increasing pregnancy rates in infertile women under IUI treatment -Who Referred to Shariati Hospital in the year of 1397 was checked

Design

Controlled clinical trial with parallel group, double-blind, randomized (with table of random numbers)

Settings and conduct

In this study, 122 women with infertility under IUI treatment - who referred to Shariati Hospital in the year of 1397- was selected randomly and was treated with 2.5 mg letrozole tablets from day 3-7 of menstrual cycle. Endometrial biopsy randomly is done for 61 patients on their ninth day of cycle; and for 61 other patients, the biopsy will not be done. After at least one follicle reached a size of above 18-20 mm, 250cc HCG injections prescribed. 24-36 hours later, IUI done. Two weeks after the intervention, serum Beta-HCG was checked

Participants/Inclusion and exclusion criteria

Inclusion criteria included: age less than 30 years with Irregular menstruation, BMI less than 40 years, the normal uterine cavity and normal tests. Exclusion criteria included: tubal obstruction and infertility with male factor.

Intervention groups

Group 1: Perform biopsy before intervention IUI Group 2: IUI intervention without biopsy

Main outcome variables

Positive serum beta-hCG, formation gastrointestinal sac , abortion and endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160224026750N2**

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

Registration timing: **prospective**

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

Update count: **0**

Registration date

2018-11-21, 1397/08/30

Registrant information

Name

Somayeh Moradpanah

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 5060

Email address

safdaria@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Thesis references

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Endometrial biopsy in increasing pregnancy rates in infertile women under intra uterin insemination treatment

Public title

The effect of endometrial biopsy in increasing pregnancy before intra uterin insemination treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 40 years irregular menstruation BMI <30 normal Hystrosalpingography normal pop smear normal uterine cavity normal FSH, normal LH, normal estradiol and TSH, normal prolactin, AMH> 1 normal sperm analysis.

Exclusion criteria:

infertility with male factor tubal factor infertility ovarian cysts

Age

From **18 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation was done to the study groups.
Randomized random numbers were used to randomize.

Blinding (investigator's opinion)

Double blinded

Blinding description

The results evaluator and patients did not know how to intervene.code was defined for the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics of Tehran University of Medical Siences

Street address

Qods Street , Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417614418

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

IR.TUMS.REC.1394.1569

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Positive test for blood beta hCG

Timepoint

20 days After intervention

Method of measurement

Blood Test

2

Description

formation gestational sac

Timepoint

34 days after intervention

Method of measurement

Ultrasound

3

Description

Endometrial Thickness

Timepoint

2 days after intervention

Method of measurement

ultrasound

Secondary outcomes

1

Description

Abortion

Timepoint

3 months and 20 days after intervention

Method of measurement

Clinical Symptoms And Vaginal Ultrasound

Intervention groups

1

Description

For 61 patients in the intervention group endometrial biopsy is done before IUI

Category
Treatment - Other

2

Description
Control group: IUI without endometrial biopsy is performed for 61 patients.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Somayeh Moradpanah

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Shariati Hospital , Jalal Al Ahmad Intersection , Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr MasoudYounesian

Street address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source

Deputy Research 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
Shariati Hospital

Full name of responsible person
Somayeh Moradpanah

Position
Obstetrics and Gynecology Surgeon

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Gynecology and Obstetrics

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Shariati Hospital, Jalal Al Ahmad Intersection, Tehran

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Province

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not 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

No - There is not 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

No - There is not a plan to make this available