

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of endometritis treatment on infertility in patients candidate for IVF and ICIS

Protocol summary

Study aim

To evaluate the effect of endometritis treatment on infertility in IVF and ICIS candidates

Design

In this study, 176 women who referred to Infertility Center of Besat Hospital in Sanandaj for treatment of infertility were included. The inclusion criteria for the study was 44 years old. Women older than 44 years were excluded from the study. Patients were divided randomly into intervention and control groups. For patients randomization, patients who referred to infertility clinic in a couple days were allocated in intervention group and patients who referred to infertility clinic on odd days were allocated in control group.

Settings and conduct

The study site was Sanandaj city.

Participants/Inclusion and exclusion criteria

Women with infertility and 44 years of age were enrolled in the study and women over 44 years of age were excluded.

Intervention groups

For patients in the intervention group, an endometrial biopsy was performed using pipelle curette on days 8 to 12 of the menstrual cycle. Then the cervix was washed with iodine. One month after performing endometrial biopsy the embryo was transferred. No intervention was performed for patients in control group, only embryo transfer was performed.

Main outcome variables

Pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012789N17**

Registration date: **2018-02-03, 1396/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-03, 1396/11/14**

Update count: **0**

Registration date

2018-02-03, 1396/11/14

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4654

Email address

rasolabady@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

2017-11-06, 1396/08/15

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

empty

Scientific title

The effect of endometritis treatment on infertility in patients candidate for IVF and ICIS

Public title

The effect of endometritis treatment on infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

44 years old women with infertility.

Exclusion criteria:
Age over 44 years

Age
From **24 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyster

Sample size

Target sample size: **176**
More than 1 sample in each individual
Number of samples in each individual: **88**
Patients with infertility
Actual sample size reached: **176**
More than 1 sample in each individual
Actual sample size in each individual: **176**
Patients with infertility

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into intervention and control groups using simple randomization. Patients who referred to infertility clinic in a couple days were allocated in the intervention group and patients who referred to infertility clinic on odd days were allocated in control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were unaware of grouping, but the researcher was aware of the patients grouping.

Placebo

Not used

Assignment

Other

Other design features

In this study, biopsy specimens were examined both pathologically and microbial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR. MUK. REC. 1396/213

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Pregnancy

Timepoint

Two weeks after the intervention and the sixth or seventh week in case of pregnancy

Method of measurement

Performing a pregnancy test two weeks after the last menstrual period and in case of pregnancy performing Fetal Heart Ultrasound at the sixth or seventh week of pregnancy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients in the intervention group, an endometrial biopsy was performed using pipelle curette on days 8 to 12 of the menstrual cycle. Then the cervix was washed with iodine. One month after performing endometrial biopsy the embryo was transferred .

Category

Treatment - Other

2

Description

Control group: No intervention was performed for patients in control group, only embryo transfer was performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Besat Hospital

Full name of responsible person

Fatemeh Tahmasebi

Street address

Keshavarz St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research of Kurdistan University of Medical Science

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Fatemeh Tahmasebi

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fariba Seyedoshohadaie

Position

Associate professor

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

Sanandaj University of Medical Sciences

Full name of responsible person

Fatemeh Tahmasebi

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data on the primary outcome (pregnancy) is for sharing.

When the data will become available and for how long

One year after the publication the data will be available.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Dr. Fatemeh Tahmasebi Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran Mobile: 00989185220653 Email: f.tahmasebi@muk.ac.ir

What processes are involved for a request to access data/document

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email and mobile phone.

Comments