Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 analyser

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
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Sponsors / Funding sources

1

Sponsor

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
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
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Fatemeh Tahmasebi
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Resident of Obstetrics and Gynecology
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Person responsible for updating data

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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