Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of low dose aspirin on pregnancy rate in frozen-thawed embryo transfer cycles

Protocol summary

Study aim
Determining the effect of low dose aspirin on clinical pregnancy rate in frozen-thawed embryo transfer cycles.

Design
Randomized clinical trial with case group and control group with parallel therapies

Settings and conduct
This study is carried out at Yazd Research and clinical Center for Infertility (Research Institute for Reproductive Sciences). Patients in frozen-thawed embryo transfer cycle are divided into case and control groups. In the case group, 6 mg of estradiol valerate (oral estradiol valerate 2 mg every eight hours) and 1 mg of folic acid and 80 mg of aspirin are prescribed daily. In the control group, 6 mg of estradiol valerate and 1 mg of folic acid are prescribed daily.

Participants/Inclusion and exclusion criteria
In this study, 130 infertile women included based on inclusion criteria: age between 18 to 40 years old, at least two embryos transferable in a frozen-thawed cycle, no history of uterine surgery or anomalies, and uterine adhesions, no history of repeated abortions, no history of endometriosis, and absence of contraindication for aspirin use (which are candidates for embryo transfer in frozen-thawed cycles is randomly divided into two groups (A, 65, and B, 65 controls). Patients with oocyte donation and untreated thyroid disorders excluded from study

Intervention groups
In the case group, for the preparation of the endometrium, in addition to the tablet of estradiol valerate and folic acid, aspirin tablets (80 mgstart) start from the previous cycle. In the control group only estradiol valrate and folic acid are prescribed.

Main outcome variables
Endometrial thickness is measured on day 13 of cycle . On the transfer day , Endometrial thickness is measured in both groups. Chemical pregnancy is investigated 14 days after embryo transfer by beta-hCG test and, if it was positive two weeks later, clinical pregnancy checked by fetal hearth rate in sonography.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190409043207N1**
Registration date: **2019-04-24, 1398/02/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-24, 1398/02/04**
Update count: **0**

Registration date
2019-04-24, 1398/02/04

Registrant information

Name
Soheila Pourmasumi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-22, 1398/02/02

Expected recruitment end date
2019-08-24, 1398/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of low dose aspirin on pregnancy rate in frozen-thawed embryo transfer cycles

Public title
The effect of aspirin on pregnancy rate in frozen-thawed embryo transfer cycles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women At least two embryos transferable in a freeze-thaw cycle No history of uterine surgery or anomalies and uterine adhesions No history of recurrent abortions No history of endometriosis Absence of contraindication for aspirin use Age between 18 and 40 years
Exclusion criteria:
Age
From **18 years** old to **39 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
By random number table couples that participated in the study divided into experiments and control groups.
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
Shahid Sadoughi University of Medical Sciences
Street address
Bouali Ave, Safayeh.
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2019-04-07, 1398/01/18
Ethics committee reference number
IR.SSU.RSI.REC.1398.003

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97.2
ICD-10 code description
Female infertility of uterine origin

Primary outcomes

1

Description
Chemical pregnancy rate
Timepoint
14 days after embryo transfer
Method of measurement
positive B-HCG

Secondary outcomes

1

Description
clinical pregnancy rate
Timepoint
4 weeks after embryo transfer
Method of measurement
fetal heart rate in sonography

Intervention groups

1

Description
Intervention group: 6 mg estradiol valerate (oral estradiol valerate 2 mg every eight hours) and 1 mg folic acid and 80 mg aspirin daily
Category
Treatment - Drugs

2

Description
Control group: 6 mg estradiol valerate (oral estradiol valerate 2 mg every eight hours) and 1 mg folic acid
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Research and Clinical center for infertility

Full name of responsible person
Dr Robab Davar

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Sponsors / Funding sources

1

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Dr maryam Mortazavi

Position
Associate professor

Latest degree
Specialist

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data obtained from this study will be released after being unidentified studies participants.
When the data will become available and for how long
Get started 6 months after publishing study results
To whom data/document is available
The findings of this study will be accessible to all individuals.
Under which criteria data/document could be used
To improve pregnancy outcomes in infertility clinics
From where data/document is obtainable
Yazd Research and Clinical Center for Infertility
What processes are involved for a request to access data/document
Receiving the author's confirmation and obtaining approval from the director of the Yazd Infertility Clinic
Comments