

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 mg start) start from the previous cycle. In the control group only estradiol valerate 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 heart 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

Country

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

Street address

Bu ali Ave, Safaeieh.

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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

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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Other areas of specialty/work

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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