Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of corticosteroids in improving the results of embryo transfer in infertile patients with endometriosis in Akbarabadi Hospital, Tehran.

Protocol summary

Study aim

Determining the effect of corticosteroids in improving fertility results from frozen embryo transfer in infertile patients with endometriosis

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 101 patients. Rand function of Excel software was used for randomization.

Settings and conduct

Two groups of infertile patients with pelvic endometriosis in the infertility department of Akbarabadi Hospital in Tehran before the start of the frozen embryo transfer cycle were subjected to suppression treatment with three monthly doses of GNRH economizer for three months and 10 weeks after taking GNRH agonist to the intervention group of 2.5 ml Gram prednisolone was given orally. The results of embryo transfer in two groups have been compared.

Participants/Inclusion and exclusion criteria

Entry conditions: women aged 20 to 40 years and having evidence of endometriosis based on laparoscopy evidence, conditions of non-entry: absence of severe sperm disorder in the patient's wife, absence of thrombophilia and autoimmune disease, absence of hormonal medication and immunosuppression in the patient, and patient's lack of consent

Intervention groups

Two groups of infertile patients with endometriosis who are candidates for embryo transfer, the intervention group receives corticosteroids and the control group receives placebo

Main outcome variables

chemical pregnancy; Clinical pregnancy; ongoing pregnancy; Miscarriage; Live birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231015059725N1**
Registration date: **2023-11-02, 1402/08/11**
Registration timing: **retrospective**

Last update: **2023-11-02, 1402/08/11**
Update count: **0**

Registration date

2023-11-02, 1402/08/11

Registrant information

Name

Azadeh Shiralizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3627 2597

Email address

azadehshiralizadeh96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

2022-04-09, 1401/01/20

Actual recruitment end date

2023-09-11, 1402/06/20

Trial completion date

2023-09-25, 1402/07/03

Scientific title
Investigating the effect of corticosteroids in improving the results of embryo transfer in infertile patients with endometriosis in Akbarabadi Hospital, Tehran.

Public title
Effect of corticosteroid in improving the results of embryo transfer in patients with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 40 years Having endometriosis based on laparoscopic evidence

Exclusion criteria:
presence of severe sperm disorders in the patient's wife based on WHO 2021 criteria congenital or acquired uterine anomalies in the patient Suffering from thrombophilic diseases such as hemophilia Suffering from autoimmune diseases such as lupus The use of hormonal treatments by the individual Taking immunosuppressant drugs by the individual

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Actual sample size reached: **101**

Randomization (investigator's opinion)
Randomized

Randomization description
First, we create a table of random numbers using a computer, then we randomly select a number from the table of real numbers for the first patient after obtaining informed consent for random allocation. For the next patients, we move one house to the right in the table of random numbers, and if the numbers are even, they will be assigned to the intervention group, and if the numbers are odd, they will be assigned to the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The blinding of the study was such that the outcome evaluator and the data analyst did not know about the content of the intervention. When prescribing the drug, the drug was given to the patient by the researcher for administration by mentioning the drug dosage and the method of administration. The outcome evaluator recorded the outcome based on the patient's identification number according to the randomization table, and the collected data was provided to the data analyst based on the number and mention of the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2021-10-07, 1400/07/15

Ethics committee reference number
IR.IUMS.FMD.REC.1400.388

Health conditions studied

1

Description of health condition studied
Endometriosis and infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Chemical pregnancy

Timepoint
Pregnancy check with beta hCG test two weeks after embryo transfer

Method of measurement
Beta hCG test

2

Description
Abortion

Timepoint
Continued pregnancy up to 20 weeks

Method of measurement
Examining the view of a live fetus with ultrasound

3

Description
Live birth
Timepoint
Pregnancy with a gestational age of more than 28 weeks
Method of measurement
Examining the live fetus with ultrasound

4

Description
Clinical pregnancy
Timepoint
Sonography 6 weeks later beta hCG positive
Method of measurement
Visualization of fetal heart rate by ultrasound

5

Description
Ongoing pregnancy
Timepoint
Continued pregnancy up to 12 weeks
Method of measurement
Ultrasound visualization of a live fetus at 12 weeks

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infertile endometriosis patients and candidates for embryo transfer treated with Differlin 3.75 in three doses with an interval of one month and then 10 weeks later starting the first dose of Differlin treated with methylprednisolone 2.5 mg daily until the fetal heart is seen. In the ultrasound, the medicine is taken and then it is stopped little by little.
Category
Treatment - Drugs

2

Description
Control group: Infertile endometriosis patients and candidates for embryo transfer are treated with 3 doses of 3.75 mg Differlin ampoules every month for 3 months, and then they will undergo embryo transfer after receiving the third dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Department of Akbarabadi Hospital, Tehran
Full name of responsible person
Mona Mortezapur
Street address
Molavi Ave,shahid akbarabadi hospital
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
akbarisene.a@iums.ac.ir
Web page address
https://akbarabadihospital.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hosein keyvani
Street address
Hemat Highway, next to Milad Tower, Iran University of Medical Sciences, 5th floor
City
Tehran
Province
Tehran
Postal code
1449614535
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+98 21 8670 2504
Email
azadehshiralizadeh96@gmail.com
Web page address
https://iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice President of Research and Technology of Iran 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
Iran University of Medical Sciences

Full name of responsible person
Azadeh Shiralizadeh

Position
Resident

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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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available