

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of oral Medroxyprogesterone acetate effect in the prevention of premature LH surge in IVF cycles in comparison with antagonist protocol

Protocol summary

Study aim

To investigate the use of medroxyprogesterone acetate (MPA) to prevent LH surge during controlled ovarian hyperstimulation in IVF cycles

Design

This study is a double-blind randomized clinical trial, in which 100 eligible patients will be randomly assigned to the intervention and control groups.

Settings and conduct

The eligible patients with infertility who are candidates for IVF at Zeinabye Hospital of Shiraz University of Medical Sciences will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the simple randomization.

Participants/Inclusion and exclusion criteria

inclusion criteria: age under 42 years regular menstrual cycles over the previous 3-month period antral follicle count (AFC) of 7-24 on menstrual cycle day 2-3 Normal TSH and Prolactin levels Exclusion criteria: endometriosis grade 3 or higher diagnosis of polycystic ovarian syndrome presence of the ovarian cyst hormone treatment receipt within the previous 3-month period low ovarian reserve (AMH<1.1 or AFC<7) any contraindication to ovarian stimulation treatment basal serum FSH concentration of more than 10 IU/L

Intervention groups

Intervention Group: use of Medroxyprogesterone acetate tablet Control Group: use of GnRH antagonist

Main outcome variables

number of oocytes retrieved

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191205045621N2**

Registration date: **2020-05-24, 1399/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-24, 1399/03/04**

Update count: **0**

Registration date

2020-05-24, 1399/03/04

Registrant information

Name

Shokufe Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

jafarish@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral Medroxyprogesterone acetate effect in the prevention of premature LH surge in IVF cycles in comparison with antagonist protocol

Public title

Effect of medroxyprogesterone acetate in the prevention of premature LH surge in IVF cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age under 42 years regular menstrual cycles over the previous 3-month period antral follicle count (AFC) of 7-24 on menstrual cycle day 2-3 Normal TSH and Prolactin levels

Exclusion criteria:

endometriosis grade 3 or higher diagnosis of polycystic ovarian syndrome presence of ovarian cyst hormone treatment receipt within the previous 3-month period low ovarian reserve (AMH<1.1 or AFC<7) any contraindication to ovarian stimulation treatment basal serum FSH concentration of more than 10 IU/L

Age

To **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyst
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Patients will be recruited consecutively and allocated to one of the two groups in an alternating fashion. Odd-numbered participants will be allocated to the MPA group and even-numbered participants will be assigned to the Antagonist protocol.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be aware of the type of medication they receive and the second executor of the research project will collect primary data at the end of the treatment without knowledge of the two groups. Also the data will be analyzed without any information about group selection.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz university of Medical Science

Street address

Zand street- central building of Shiraz University of Medical Sciences-Shiraz

City

Shiraz

Province

Fars

Postal code

197871345

Approval date

2019-12-15, 1398/09/24

Ethics committee reference number

IR.SUMS.MED.REC.1398.513

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

number of oocytes retrieved

Timepoint

on day of oocyte retrieval

Method of measurement

count

Secondary outcomes

1

Description

number of mature oocytes

Timepoint

on day of oocyte retrieval

Method of measurement

count

2

Description

clinical pregnancy

Timepoint

3 weeks after IVF

Method of measurement

Measurement of beta-hCG

3

Description

Embryos number

Timepoint

after 24 hours and day 5

Method of measurement

microscopic evaluation

4

Description

fertilization rate

Timepoint

24 hours after intra-cytoplasmic sperm injection

Method of measurement

microscope

5

Description

implantation rate

Timepoint

2 weeks after embryo transfer

Method of measurement

Measurement of beta-hCG

Intervention groups

1

Description

Intervention group: the group will be administered hMG (150-225 IU) and MPA (10 mg/d) from MC3 onward

Category

Treatment - Drugs

2

Description

Control group: the group will be administered hMG (150-225 IU) and Triptorelin 0.1 mg SQ and 1500 IU hCG

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Zeinabiyeh Hospital

Full name of responsible person

Mina Moosaie

Street address

Zeinabye Street

City

Shiraz

Province

Fars

Postal code

۷۱۵۳۸۱۳۳۱۱

Phone

+98 71 3726 6811

Email

zeinabhp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yoones Ghasemi

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mina Moosaie

Position

Resident

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
Shiraz University of Medical Sciences
Full name of responsible person
Mina Moosaie
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohsen Reza Moosaie

Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available