

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Review and comparison the success rate, using medroxy progesterone acetate instead of GNRH antagonis, in patients undergoing intracytoplasmic sperm injection (ICSI) by using oocyte donation, single-blind clinical trial

Protocol summary

Study aim

Review and comparison the success rate, using Medroxyprogesterone acetate instead of GNRH antagonist in patients undergoing ICSI by using oocyte donation

Design

Clinical trial with control group, with parallel groups, single- blind, randomized

Settings and conduct

All infertile patients with oocyte donation undergoing ICSI, they are referred to private infertility clinic of Rasht, which are selected according to inclusion criteria. After giving explanations to individual, they are randomly divided. Intervention groups are aware of how to intervene. To intervene to participants Medroxyprogesterone acetate is prescribed and Fertility success will be measured through transvaginal ultrasound and fetal heart rate monitoring.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all infertile patients with oocyte donation undergoing ICSI. Exclusion criteria: all patients are in case of side effects of the drug or lack of regular use of the drug.

Intervention groups

Intervention group: all infertile patients with oocyte donation under ICSI, which received 2 tablets of Medroxyprogesterone from the first day of the visit until the injection of HCG. The control group will receive the usual treatment.

Main outcome variables

Fertility success

General information

Reason for update

Due to achieving sufficient sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20081007001306N10**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**

Update count: **1**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Ziba Zahiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

drzibazahiri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Review and comparison the success rate, using medroxy progesterone acetate instead of GNRH antagonis, in patients undergoing intracytoplasmic sperm injection (ICSI) by using oocyte donation, single-blind clinical trial

Public title

Review and comparison the success rate, using medroxy progesterone acetate instead of GNRH antagonist, in patients undergoing intracytoplasmic sperm injection (ICSI) by using oocyte donation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All infertile patients with oocyte donation undergoing ICSI

Exclusion criteria:

In the oocyte donor: Age over 35 years, irregular menstruation, antral follicle count less than 5 and more than 12, FSH more than 10 on the third day of menstruation, cystic ovaries and endometriosis, BMI greater than 25, not having at least one child and the presence of any disease affecting ovulation (such as thyroid disease and high prolactin levels) In the oocyte receptor: Age over 50 years , any systemic disease including hypertension, diabetes, chronic diseases, liver and kidney, problem in the uterus and tubes (including: leiomyoma, polyp, adenomyosis, ashren and hydrosalpinx and etc.) and there is male factor

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be generated by Random Allocation software, each of which is placed in a separate package according to the software list and closed it and gave it to a third person . In case of referral of the patient and his eligibility, the envelope is opened and It is treated based on the desired sequence without notice of the next treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Analyst will be unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave

City

Rasht

Province

Guilan

Postal code

66949- 41446

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.GUMS.REC.1398.148

Health conditions studied

1

Description of health condition studied

Infertility in female

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Fertility success

Timepoint

Two weeks after fetal transfer

Method of measurement

Pregnancy test

Secondary outcomes

1

Description

Seeing fetal heart rate

Timepoint

6 weeks after fetal transfer

Method of measurement

Vaginal ultrasound

Intervention groups

1

Description

Intervention group: prescription two tablets of Medroxyprogesterone containing 5 mg; manufactured by Abouryan company; Iran; from the first day of the visit until receiving HCG

Category

Treatment - Drugs

2

Description

Control group: Receive routine treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Ziba Zahiri

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3th Floor, Busar Building, Golsar Cross St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice-chancellorship, Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

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Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave

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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

Research vice-chancellorship, Guilan 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

Rasht University of Medical Sciences

Full name of responsible person

Ziba Zahiri

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Ziba Zahiri

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

Candidate, MS of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Al-Zahra hospital, Namjoo Ave

City**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

The release plan is still unknown

Study Protocol

Undecided - It is not yet known if there will be 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