Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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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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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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
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Position
Full Professor
Latest degree
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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
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