Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of reduced dose of long-acting gonadotropin releasing hormone (GnRH) agonist versus short acting GnRH agonist on pregnancy outcome in patients undergoing intracytoplasmic sperm injection outcome- clinical trial

Protocol summary

Study aim

The aim of present study is to evaluate the effect of reduced dose of long-acting gonadotropin releasing hormone (GnRH) agonist versus short acting GnRH agonist on pregnancy outcome in patients undergoing intracytoplasmic sperm injection outcome.

Design

Phase III, with a parallel group, double blinded, randomized clinical trial with 400 participants in two groups of long (n=200) and short-acting gonadotropin releasing hormone (GnRH) agonist (n=200)

Settings and conduct

The aim of present study is to evaluate the effect of reduced dose of long-acting gonadotropin releasing hormone (GnRH) agonist versus short acting GnRH agonist on pregnancy outcome in patients undergoing intracytoplasmic sperm injection outcome at Mehr medical institute. Block randomization will be done with a 4:4 allocation ratio. The physicians and patients will be blinded to group assignment.

Participants/Inclusion and exclusion criteria

Normal responders to ovarian induction Inclusion criteria: Age ≤ 40 years, Basal FSH level <8, Less than one failed ICSI cycle, Non PCOS patients, No azoospermia, No moderate to severe endometriosis Exclusion criteria: No response to ovulation induction, Difficult embryo transfer, Bloody embryo transfer

Intervention groups

First group: long-acting gonadotropin releasing hormone (GnRH) agonist Second group: short-acting gonadotropin releasing hormone (GnRH) agonist

Main outcome variables

Biochemical and clinical pregnancy rate will be considered as main endpoint.

General information

Reason for update

Completion of the project

Acronym

IRCT registration information

IRCT registration number: **IRCT20190609043845N1**
Registration date: **2019-06-20, 1398/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**
Update count: **2**

Registration date

2019-06-20, 1398/03/30

Registrant information

Name

Roya Kabodmehri

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-29, 1398/05/07

Expected recruitment end date

2020-01-27, 1398/11/07

Actual recruitment start date

2019-07-29, 1398/05/07

Actual recruitment end date

2020-02-17, 1398/11/28

Trial completion date

2020-07-28, 1399/05/07

Scientific title

Evaluation of the effect of reduced dose of long-acting gonadotropin releasing hormone (GnRH) agonist versus short acting GnRH agonist on pregnancy outcome in patients undergoing intracytoplasmic sperm injection outcome- clinical trial

Public title

Effect of reduced dose of long-acting GnRH agonist versus short acting GnRH agonist

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≤ 40 years Basal FSH level <8 Less than one failed ICSI cycle Non PCOS patients No azoospermia No moderate to severe endometriosis

Exclusion criteria:

No response to ovulation induction Difficult embryo transfer Bloody embryo transfer

Age

To **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **400**

Actual sample size reached: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done with a 4:4 allocation ratio.(https://www.sealedenvelope.com)

Blinding (investigator's opinion)

Double blinded

Blinding description

Each patient will have an identification code (IC) which will be placed in sealed envelope by researcher. Also, medications will be placed in sealed containers with IC. The physicians and patients will be blinded to group assignment.

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 and technology of Guilan university of medical sciences, Shahid Siadati avenue, Namjoo street, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.GUMS.REC.1398.094

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Biochemical pregnancy rate

Timepoint

Two month after intervention

Method of measurement

Positive βhCG test (Lab kit)

2

Description

Clinical pregnancy rate

Timepoint

Two month after intervention

Method of measurement

Assessment of gestational sac and fetal heartbeat at 7 weeks of gestation (Vaginal ultrasonography)

Secondary outcomes

1

Description

Gonadotropin dosage

Timepoint
At the end of ovarian induction cycle
Method of measurement
Total number of ampoule

2

Description
Duration of ovarian induction
Timepoint
At the end of ovarian induction cycle
Method of measurement
Number of days

Intervention groups

1

Description
Intervention group: long-acting gonadotropin releasing hormone (GnRH) agonist: Decapeptyl (1.25mg, Ferring) will be injected on 21st day of menstruation before the start of ovarian induction cycle.
Category
Treatment - Drugs

2

Description
Intervention group: short-acting gonadotropin releasing hormone (GnRH) agonist: Cinnafact (Cinnagen) will be injected on 21st day of previous menstrual cycle at starting dose of 0.5 mg/daily and continued 0.25 mg/daily from 2st day of menstruation until the day of hCG administration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Medical Institute
Full name of responsible person
Roya Kabodmehri
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Reproductive Health Research Center, Alzahra Hospital, Namjoo Street, Rasht, Guilan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
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Research and Technology at Guilan University of Medical Sciences, Shahid Siadati avenue, Namjoo street, Rasht, Guilan, Iran
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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
Guilan University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Mehr Fertility Research Center
Full name of responsible person
Marzieh Mehrafza
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Mehr Fertility Research Center, Mehr Medical Institute, Ershad St., Shahid Ansari Blvd., Rasht, Iran
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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
Mehr Fertility Research Center
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Roya Kabodmehri
Position
Assistant Professor
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Study Protocol and Clinical Study Report

When the data will become available and for how long

Starting after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Starting after publication

From where data/document is obtainable

Roya Kabodmehri

What processes are involved for a request to access data/document

Email

Comments