Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of adding low dose human Chorionic Gonadotropin (hCG) to recumbinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle, a clinical trial.

Protocol summary

Summary

This research is done to examine the effect of adding low dose human Chorionic Gonadotropin (hCG) to recombinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle. This research is randomized double blind controlled clinical trial. Our trial performs in Fateme Zahra Reproductive Research Center in Babol, Iran. Patients with these inclusion criteria: 20 – 40 years old; normal salpingography are selected and randomly divided in three groups. Exclusion criteria include history of previous chronic disease. Patients randomly placed in to three groups of 50 women. In all three groups all patients treated with a dose of 150 International Unit (IU) rFSH per day. In the first group or control group treatment with rFSH will continue until the creation of the oocytes. In the second group when the follicle size become 14 millimeter, rFSH dose reduce to 75 IU per day and treatment starts with 100 IU hCG per day. In the third group when follicle size become 14 millimeter, treatment with rFSH stops and patient treat with 200 IU hCG per day. Gonadotropin administration continues to mature follicles. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed. Oocyte maturation, ovarian hyperstimulation syndrome and follicular response will compare in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012932284N1**
Registration date: **2017-03-07, 1395/12/17**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-03-07, 1395/12/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences.

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding low dose human Chorionic Gonadotropin (hCG) to recumbinant Follicular Stimulating Hormone (rFSH) on follicular phase in women undergoing intracytoplasmic sperm injection cycle, a clinical trial.

Public title

Effect of human Chorionic Gonadotropin (hCG) on treatment of infertility

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: 20 - 40 years old; 1 year history of infertility; candidate for intracytoplasmic sperm injection. Exclusion Criteria: history of chronic disease; abnormal salpingography.

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol Univercity of Medical Sciences

Street address
Rohani hospital, Ganjafrooz street, Babol

City
Babol

Postal code
4717647745

Approval date
2016-07-13, 1395/04/23

Ethics committee reference number
mubabol.hri.rec.1395.54

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
n97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Follicle size

Timepoint
Daily

Method of measurement
Ultrasonography - Milimeter

2

Description
Mature oocyte

Timepoint
End of Cycle

Method of measurement
Sonography

Secondary outcomes

1

Description
Ovarian Hyperstimulation Syndrome

Timepoint
Daily

Method of measurement
Sonography - Folicle size - Milimeter

Intervention groups

1

Description
In the first group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. Treatment with rFSH will continue until the creation of the oocytes. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU human Chorionic Gonadotropin (hCG) will inject. Thirty six hours later ovarian puncture is performed

Category
Treatment - Drugs

2

Description
In the second group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. When the follicle size become 14 millimeter, rFSH dose reduce to 75 IU per day and treatment starts with 100 IU human Chorionic Gonadotropin (hCG) per day. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed.

Category
Treatment - Drugs

3

Description
In the third group patients treated with a dose of 150 International Unit (IU) recombinant Follicular Stimulating Hormone (rFSH) per day. When follicle size become 14 millimeter, treatment with rFSH stops and patient treat with 200 IU human Chorionic Gonadotropin per day. When at least two or three follicles 18 millimeter to 20 millimeter in size were formed; 100 IU hCG will inject. Thirty six hours later ovarian puncture is performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemezahra Infertility and Reproductive Health Research Center
Full name of responsible person
Dr. Maryam Yeganegi
Street address
Torkmahalle, 3 Km after Mohammad Hassan Khan Bridge, Babol, Mazandaran,Iran
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Babol University of Medical Science
Full name of responsible person
Dr Ali Bijani
Street address
Babol University of Medical Science, Ganjafrooz Street,
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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
Vice Chancellor for Research, Babol University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty