Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

comparison of ovulation triggering outcome using these two methods: standard dose of human chorionic gonadotropin and human chorionic gonadotropin In combination with gonadotropin releasing hormone in IVF/ICSI cycles

Protocol summary

Study aim
comparison of ovulation triggering outcome using these two methods: standard dose of human chorionic gonadotropin and human chorionic gonadotropin In combination with gonadotropin releasing hormone in IVF/ICSI cycles

Design
This will be a two arm parallel group design of 100 patients candidate of IVF/ICSI , single blind randomised trial, with a computer-generated randomization list with a block size of 4, with 1:1 allocation.

Settings and conduct
Infertile women candidates of IVF/ICSI for different reason, having the study criteria who come to infertility clinic of Alzahra hospital will be entered into the study. First we will take an informed written consent and all part of the study will be explained to the patient. The treatment allocation will be placed in a sealed opaque envelope and picked up consecutively.

Participants/Inclusion and exclusion criteria
women who are candidate of IVF/ICSI and have some risk of ovarian hyperstimulation syndrome (OHSS) will be entered in the study. Every body who has diminished ovarian reserve [antral folicular count (AFC) less than 4 or anti-mulerian hormone (AMH) less than 1] will be excluded.

Intervention groups
during ovarian stimulation and ultrasound control when there is at least 5 or more follicles above 17 mm in diameter we administer 0.2 mg decapeptide and 2500 unit HcG for triggering ovulation in the study group or 2 ampoules of 5000 unit HcG equivalent to 10,000 units HcG in the control group.

Main outcome variables
number and quality of oocytes؛ number and quality of embryos؛ fertilization rate؛ imlantation rate؛ the rate of OHSS

General information

Reason for update
increment of the sample size and change in the dose of the drug in the control and intervention group because of the mistake in typing

Acronym

IRCT registration information
IRCT registration number: **IRCT20101227005485N7**
Registration date: **2019-07-18, 1398/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**
Update count: **1**

Registration date
2019-07-18, 1398/04/27

Registrant information

Name
Nazli Navali

Name of organization / entity
Tabriz University of Medical Sciences, Faculty of Medecine

Country
Iran (Islamic Republic of)

Phone
+98 41 1330 2879

Email address
navalin@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of ovulation triggering outcome using these two methods: standard dose of human chorionic gonadotropin and human chorionic gonadotropin In combination with gonadotropin releasing hormone in IVF/ICSI cycles

Public title

comparison of standard dose of human chorionic gonadotropin and human chorionic gonadotropin In combination with gonadotropin releasing hormone in IVF/ICSI cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

women who are candidate of IVF/ICSI and have some risk of OHSS will be entered in the study.

Exclusion criteria:

every body who have diminished ovarian reserve. (AFC<4 or AMH<1)

Age

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

Gender

Female

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-generated randomization list with a block size of 4, with 1:1 allocation will be used to randomize patients. In such a case, one control will be checked for each intervention and with each of the 4 patients enrolled in the study, the two groups are balanced in terms of control and intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

The treatment allocation will be placed in a sealed, opaque, envelope and picked up consecutively. in the manner that the participant, the outcome evaluator and the analyzer will not be aware of the type of the drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.TBZMED.REC.1398.129

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

number and quality of resulted oocytes

Timepoint

the day of oocytes pick up

Method of measurement

microscopic evaluation

2

Description

fertilization rate

Timepoint

24 hours after intra-cytoplasmic sperm injection

Method of measurement

microscope

3

Description
implantation rate
Timepoint
2 weeks after embryo transfer
Method of measurement
Measurement of beta-hCG

4

Description
number and quality of embryos
Timepoint
after 24 hours, day 3 and day 5
Method of measurement
microscopic evaluation

Secondary outcomes

1

Description
ovarian hyperstimulation syndrome
Timepoint
the day of oocyte pick-up and a week later
Method of measurement
history, physical examination and laboratory tests

Intervention groups

1

Description
Intervention group: 2500 unit human chorionic gonadotropin In combination with 0.2 miligram gonadotropin releasing hormone
Category
Treatment - Drugs

2

Description
Control group: 10000 unit human chorionic gonadotropin for triggering
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Navali Nazli
Street address
south Artesh street
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3554 1221
Email
navalin@tbzmed.ac.ir
Web page address
http://alzahrahosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Elahe Saheb Olad Madarek
Street address
Artesh street
City
Tabriz
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East Azarbaijan
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Email
navalin@tbzmed.ac.ir
Web page address
http://alzahrahosp.tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Nazli Navali
Position
infertility fellowship/associate professor
Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Artesh street, Alzahra Hospita, infertility department
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nazli Navali
Position
associate professor/infertility fellowship
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Phone
+98 41 3554 1221
Email
navalin@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
only a part of data could be shared
When the data will become available and for how long
2 years after publishing the results, the data could be attained.
To whom data/document is available
data will be given for every academic person who is interested in this field.
Under which criteria data/document could be used
for utilization in researches like in metha-analyses
From where data/document is obtainable
the applicants can mail there request to the person responsible for scientific inquiries.
What processes are involved for a request to access data/document
after application, data will be sent in two weeks.
Comments