

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 follicular 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

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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

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Artesh street, Alzahra Hospita, infertility department

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nazli Navali

Position

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Person responsible for updating data

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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 meta-analyses

From where data/document is obtainable

the applicants can mail their 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