

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Randomized clinical trial to compare Dostinex versus Quinagolide to prevention of ovarian hyperstimulation syndrome

Protocol summary

Summary

1)Objective:The aim of this study is to compare quinagolide with Dostinex in the prevention of ovarian hyperstimulation syndrome (OHSS). 2)Design:The study is a randomized clinical trial recruiting 126 patients, who have undergone assisted reproductive procedure. The study is conducting in the infertility of Shahid Beheshti. 3)Setting and conduct: All of the participants undergo controlled ovarian hyperstimulation (COH) with Gonadotropin/GnRH-antagonist protocol using recombinant-FSH. After 5 day stimulation when at least two follicles with diameter of 14mm observed, GnRH antagonist (Cetratide, Merc) or (Orgalotrone, Organon) start with a daily dose 0.25mg until administer GnRH agonist as a final oocyte maturation. The participants divide in two groups. The first group comprise 63 women treat with 0.5mg of Dostinex (Pfizer) every day for seven days commencing on the day of oocyte retrieval. If OHSS occurs, the standard conservative and supportive management for OHSS employed. The second group comprise of 63 women, the latter group receive Quinagolide 75 mg (Norprolac, Ferring, Denmark). Diagnosis of OHSS as well as its severity performed according to a standard definition 3 and 6 days after GnRH agonist administration. 4)Participants including major eligibility criteria: inclusion criteria: 20-40 years old patient; 20 oocytes when agonist GnRH start; risk of OHSS Exclusion criteria: metabolic dysfunction; hypertension; history of syncope and heart disease. 5)Intervention: first group treat with 0.5mg of Dostinex (Pfizer) every day for 7 days commencing on the day of oocyte retrieval, the second group comprise of 63 women, the latter group receive 75mg of Quinagolide for 7 days commencing on the day of oocyte retrieval. 6)Variables: nausea and vomiting; abdominal distention; hemoconcentration; ascites

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053128187N1**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Mahshid Vasef

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 3000

Email address

vasef@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Infertility & Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-03-02, 1395/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial to compare Dostinex versus Quinagolide to prevention of ovarian hyperstimulation syndrome

Public title

Dostinex versus Quinagolide for prevention of ovarian hyperstimulation syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20-40 years old patient; 20 oocytes when agonist GnRh start; risk of OHSS Exclusion criteria: metabolic dysfunction; hypertension; history of syncope; heart disease.

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: **126**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Infertility & Reproductive Health Research Center, Shahid Beheshti University o

Street address

Infertility and Reproductive Health Research Center, Shohada-e-Tajrish Hospital, Tajrish Sq, Tehran

City

Tehran

Postal code

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

ir.sbm.retech.rec.1395.542

Health conditions studied

1

Description of health condition studied

Ovarian hyperstimulation syndrom

ICD-10 code

N98.1

ICD-10 code description

Hyperstimulation of ovaries

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

3 and 6 days after drug prescription

Method of measurement

Questionnaire

2

Description

Abdominal distention

Timepoint

3 and 6 days after drug prescription

Method of measurement

Questionnaire and physical examination

3

Description

Hemoconcentration

Timepoint

3 and 6 days after drug prescription

Method of measurement

Clinical lab

4

Description

Ascit

Timepoint

3 and 6 days after drug prescription

Method of measurement

Sonography

Secondary outcomes

1

Description

Tap of ascit

Timepoint

3 and 6 days after drug prescription

Method of measurement

paracentesis

2

Description

Hospitalization

Timepoint

3 and 6 days after drug prescription

Method of measurement

Questionnaire

Intervention groups

1

Description

The first group treat with 0.5mg of Dostinex every day for seven days commencing on the day of oocyte retrieval.

Category

Treatment - Drugs

2

Description

The second group treat with 75 mg of Quinagolid every day for 7 days commencing on the day of oocyte retrieval.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility & Reproductive Health Research Center,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.R .Taheripanah. Infertility & Reproductive Health
Research Center(IRHRC) Board of Iranian Society

Street address

Infertility and Reproductive Health Research Center,
Shohada-e-Tajrish Hospita, Tajrish Sq, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Zahra Sadeghzadeh

Street address

Infertility and Reproductive Health Research Cente,
Shohada-e-Tajrish Hospita, Tajrish Sq, Tehran

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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, Shahid Beheshti University
of Medical Sciences

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

Name of organization / entity

Infertility & Reproductive Health Research
Center,Shahid Beheshti University of Medical
Sciences

Full name of responsible person

Zahra Sadeghzadeh

Position

Bachelor of Psychology

Other areas of specialty/work

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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