

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparsion of effects of Gonadotropin Releasing Hormon Agonists and Antagonists in ART cycles in patients 35 years and older

Protocol summary

Summary

Study included two group of 60 patients of infertile women 35 years old and older who fulfill inclusion criteria (infertility , 35 years old and older, without endocrine problems and hypertension and pcos (polycystic ovarian syndrome) and without any history of pelvic endometriosis or ovarian surgery are studied. patients of group one receives Gonadotropin Releasing Hormone Agonists from 21st day of cycle before of art and at 2nd or 3rd days of next cycle ,after sonography if ovaries are inactive and endometrial thickness is less than 4mm, induction ovulation with external gonadotropins take place. In second group from 2nd or 3rd days of cycle induction ovulation with external gonadotropins take place, after growth of follicles to 14mm (equal to 8th days of cycle) Gonadotropin Releasing Hormone Antagonists starts. At the end two groups are compared for number of follicles which are growth, number of obtained ovum, Estradiol levels, endometrial situation, and duration of stimulation for induction ovulation, pregnancy rate, and abortion rate before 12 weeks of pregnancy, prevalence and severity of OHSS, number of used ampoules of gonadotropins.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109136626N3**

Registration date: **2011-10-16, 1390/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-16, 1390/07/24

Registrant information

Name

Seddighe Abdollahi fard

Name of organization / entity

Tabriz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 4250

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Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center,Tabriz
University of Medical Sciences

Expected recruitment start date

2011-09-11, 1390/06/20

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of effects of Gonadotropin Releasing Hormon Agonists and Antagonists in ART cycles in patients 35 years and older

Public title

Comparsion of effects of Gonadotropin Releasing Hormon Agonists and Antagonists in ART cycles in infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:infertile women older than 35 years who are conditions for art and have not any endocreean

disease or hypertension or polycystic ovarian syndrome (pcos) or history of endometriosis or any surgery of ovarian Exclusion criteria: Infertile women smaller than 35 years old or have any endocrine disease or hypertension or polycystic ovarian syndrome (pcos) or history of endometriosis or any surgery of ovarian

Age

From **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Science

Street address

Tabriz University of Medical Science ,Golgasht ave,
Azadi ave

City

Tabriz

Postal code**Approval date**

2011-09-10, 1390/06/19

Ethics committee reference number

4686 /4/5

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

n97

ICD-10 code description

female infertility

Primary outcomes**1****Description**

Rate of documented pregnancy

Timepoint

Two months after the end of intervention

Method of measurement

Sonography

Secondary outcomes**1****Description**

Rate of abortion before 12 weeks of pregnancy

Timepoint

Four months after the end of intervention

Method of measurement

Sonography

2**Description**

Severity of ovarian hyperstimulation syndrome

Timepoint

During one month after the end of intervention

Method of measurement

By examination and sonography

3**Description**

Rate of chemical pregnancy

Timepoint

Two weeks after end of intervention

Method of measurement

unit/litter

4**Description**

Prevalence of ovarian hyperstimulation syndrome

Timepoint

During one month after the end of intervention

Method of measurement

By examination and sonography

5**Description**

Number of follicles which are growth

Timepoint

During of intervention (36 hours after hcg injection)

Method of measurement

Sonography

6**Description**

Number of the obtained ova

Timepoint

During the intervention(36 hours after hcg injection)

Method of measurement

By counting

7

Description

Estradiol levels

Timepoint

During the intervention(day of hcg injection)

Method of measurement

pg/ml

8

Description

Endometrial situation

Timepoint

During the intervention(day of hcg injection)

Method of measurement

Sonography

9

Description

Duration of the stimulation for induction ovulation

Timepoint

During the intervention

Method of measurement

Days

10

Description

Number of the ampuls of gonadotropins used

Timepoint

During the intervention

Method of measurement

By counting

Intervention groups

1

Description

Exogenic gonadotropin Gonal F 75unit IM daily and Monogon 150 unit IM daily both of them at 2th_3th of cycle if ovarians are inactive and endometial thickness is less than 4mm (in both groups)

Category

Treatment - Drugs

2

Description

Gonadotropin Releasing Hormon Agonist (superfact) 0.5 cc subcutaneus daily from 21th day of cycle until diameter of dominant follicle reaches to 18_19mm (in group one)

Category

Treatment - Drugs

3

Description

Gonadotropin Releasing Hormon Antagonist (cetrotide) 3.5mg subcutaneus single dose (in second group)

Category

Treatment - Drugs

4

Description

Human chorionic gonadotropin (hcg)(pregnil)1000 unit IM single dose ,when diameter of dominant follicle reaches 18_19mm

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AL-Zahra hospital

Full name of responsible person

Street address

Al-zahra hospital,South artesh ave, Bagh shomal crossroad,Tabriz,iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vise chancellor for research, Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht ave, Azadi ave

City

Tabriz

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

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

AL-zahra hospital,Tabriz university of medical science

Full name of responsible person

Seddighe Abdollahi

Position

Associate Professor

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