Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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dr-abdollahi@tbzmed.ac.ir

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

desease or hypertantion or polycistic ovarian syndrom(pcos) or history of endometriosis or any surgery of ovarian Exclusion criteria: Infertile women smaller than 35 years old or have any endocreean desease or hypertantion or polycistic ovarian syndrom(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 mounths after the end of intervention

Method of measurement
Sonography

Secondary outcomes

1

Description
Rate of abortion before 12 weeks of pregnancy

Timepoint
Four mounths after the end of intervention

Method of measurement
Sonography

2

Description
Severity of ovarian hyperstimulation syndrom

Timepoint
During one mounth 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
Prevalance of ovarian hyperstimulation syndrom

Timepoint
During one mounth 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 obtiened ovums

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 reachs 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 gonadothropin (hcg)(pregnil)1000 unit IM single dose ,when diameter of dominant follicle reachs 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 chanceller 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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Neda Zafarbakhsh
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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