

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

To compare outcomes between a standard protocol and a luteal phase estradiol in infertile patients with poor responders

Protocol summary

Summary

In this study we compare routine Gonadotropin releasing hormone (GnRH) agonist long protocol with Luteal phase Estradiol. 60 selected patients (poor responders referred to the Infertility Center of Fatemeh-Zahra) according to inclusion criteria (those with fewer than 5 oocytes number ...) and exclusion criteria (patient who are not satisfied to entry the study) are divided in two groups. In group1 GnRH agonist begin at 21th day of menstruation cycle and then Administration of Gonadotropin will begin at 3th day of next cycle and continue until the day of HCG injection. Group2 will use Estradiol 2mg twice a day form 21th day and continue until 3th day of Gonadotropin administration. Poor responder: Oocyte number fewer 5, Age>37, basic FSH>12, previous cancel cycle. All patients will give Vaginal ultrasound in menstruation period and then both groups will begin using of oral contraceptive LD and continue until 21th day of cycle. Then group1 and group2 protocol performs. When the largest follicle reached the 18mm a single 10000 IU of HCG will administrate. Trans-vaginal oocyte retrieval will be performed 35 hours later. 2-3 day later embryo transfer will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901311760N4**

Registration date: **2011-01-06, 1389/10/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-06, 1389/10/16

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

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+98 11 3236 2282

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zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare outcomes between a standard protocol and
a luteal phase estradiol in infertile patients with poor
responders

Public title

To compare outcomes between a standard protocol and
a luteal phase estradiol in infertile patients with poor
responders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile patients with poor ovarian response, Oocytes number<5 or age>37, Basal FSH>12 Or canceled the previous cycle. Exclusion criteria: Patients who do not consent to enter the study.

Age

From **37 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

The ethics committee of Babol University of Medical sciences

Street address

Gangafroz Avenue, Babol University of Medical sciences

City

Babol

Postal code

4717641367

Approval date

2010-07-12, 1389/04/21

Ethics committee reference number

1014

Health conditions studied

1

Description of health condition studied

poor responder patients in ART(Assisted Reproductive Technology)

ICD-10 code

E28.8

ICD-10 code description

Other ovarian dysfunction

Primary outcomes

1

Description

Number of oocytes

Timepoint

puncher day

Method of measurement

Counted by the laboratory

2

Description

Total fetus

Timepoint

2 days after puncher

Method of measurement

Counted by the laboratory

Secondary outcomes

1

Description

Pregnancy

Timepoint

17 days after embryo transfer

Method of measurement

blood BHCG test

Intervention groups

1

Description

Group 1: oral contraceptive LD; GnRH agonist injection; Gonadotropin injection; HCG injection (10000 IU Im)

Category

Treatment - Drugs

2

Description

Group2: Oral contraceptive LD; CnRH agonists injection; Oral estradiol 2mg, twice a day; Gonadotropin injection; HCG injection (10000 lu Im)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & reproductive Health Reseach Center

Full name of responsible person

Dr. maryam BaGhori

Street address

Fatemehzahra Fertility & reproductive Health

Research Center, Noshirvani street
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Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Ali bijani

Street address

Gangafroz Avenue

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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 and Technology, Babol
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

Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/Responsible for Public Affairs of Research Center

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Gynecologist

Other areas of specialty/work

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Web page address

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