

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of Delaying the oocyte maturation trigger on numbers of metaphase II oocytes based on blood progesterone level

Protocol summary

Summary

This study is a parallel randomized clinical trial among infertile patients under 40 years old who referred to research and clinical center for infertility in Yazd and candidate for IVF/ICSI. Controlled ovarian hyperstimulation was done with antagonist protocol. First sonography for follicular growth assessment was done in 7th days of stimulation and then patients were monitored every 1-2 days with sonography till at least three follicles with average diameter of 18 mm were present. Then estradiol and progesterone levels were measured. Patients with progesterone blood level equal or below 1 ng/ml entered in study. Patients were divided into two groups with Table of random numbers. Final oocyte maturation with 5000-10000 IU HCG was done at the same day in the first group (early trigger group) and 24 hours later in the second group (late trigger group). Then oocyte puncture was done. We will classify the oocytes maturation based on the morphological appearance. All of retrieved oocytes undergo IVF / ICSI. A maximum of two embryos were transferred on day 2 or 3 after oocytes were extracted. Vaginal progesterone for luteal phase support, started from the day of puncture. Pregnancy test was performed two weeks after the transfer. The main variable is the number of oocytes in metaphase II. Other variables are, the number of fertilized oocytes (2PN) and the number of embryos formed and chemical and clinical pregnancy rate in each group. These variables are then compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071628756N3**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Elham Naghshineh

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

naghshineh@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Research and Clinical Center for Infertility

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Delaying the oocyte maturation trigger on numbers of metaphase II oocytes based on blood progesterone level

Public title

Effect of Delaying the oocyte maturation trigger on numbers of mature oocytes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:infertile patients under 40 years old who refereed to research and clinical center for infertility in yazd for IVF/ICSI exclusion criteria: age over 40 years

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

shahid sadougi university of medical sciences

Street address

yazd

City

yazd

Postal code

Approval date

2016-06-12, 1395/03/23

Ethics committee reference number

17/1/80248/پ

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97.9

ICD-10 code description

female infertility-unspecified

Primary outcomes

1

Description

number of metaphase II oocytes

Timepoint

after intervention

Method of measurement

number

2

Description

number of fertilized oocytes (2PN)

Timepoint

after intervention

Method of measurement

number

3

Description

number of embryo formation

Timepoint

after intervention

Method of measurement

number

Secondary outcomes

1

Description

chemical pregnancy

Timepoint

14 days after transfer

Method of measurement

BHCG test

2

Description

clinical pregnancy

Timepoint

28 days after transfer

Method of measurement

transvaginal sonography

Intervention groups

1

Description

in the intervention group patients receive HCG to trigger final oocytes with 24-hour delay

Category

Treatment - Drugs

2

Description

In the control group receive HCG for routine final oocyte maturation on the same day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

research and clinical center of infertility

Full name of responsible person

robab darar

Street address

boo ali/saffaieh

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research and clinical center for inftrility

Full name of responsible person

alimohammadabdoli

Street address

safaieh,booali

City

yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

research and clinical center for inftrility

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

research and clinical center for inftrility

Full name of responsible person

Elham Naghshineh

Position

fellowship

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

shahid sadoughi university of medical science

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Robab Davar

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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