

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### A prospective randomized clinical trial on mid-cycle triggering of final oocyte maturation using GnRH versus HCG in Antagonist protocol

#### Protocol summary

##### Summary

Objectives: Comparing effects of GnRH agonist versus hCG in final oocyte maturation in antagonist protocol of IVF cycle. Design: In this research a comparison among abovementioned approaches for triggering of final oocyte maturation is performed based on following criteria: (1) quality and number of retrieved oocytes (2) number and quality of embryos obtained (3) clinical and ongoing pregnancy rate (4) the risk of OHSS . Setting and Conduct, Inclusion and Exclusion Criteria: Candidate women for IVF with ages lower than 39 who will refer to private infertility clinic of Madar-O-Koodak hospital affiliated to Shiraz University of Medical sciences will be enrolled. The patients with Ovulatory factor infertility, Endometriosis and uterine anomalies will be excluded from study population. The remaining patients will be randomly allocated in two groups using random table of numbers. Interventions: In control group named as HCG group will receive HCG for mid-cycle triggering of final oocyte maturation as a standard IVF protocol. In intervention group the GnRH agonist will be used for mid-cycle triggering of final oocyte maturation. Main outcome measures: clinical pregnancy, hormonal assay, rate of OHSS, Number and quality of embryos obtained

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015060222541N1**

Registration date: **2016-06-24, 1395/04/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-24, 1395/04/04

#### Registrant information

##### Name

Leila Sarikhani

##### Name of organization / entity

Shiraz Univesity of Medical School

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research , Zand street , Shiraz University of Medical Sciences

#### Expected recruitment start date

2013-02-26, 1391/12/08

#### Expected recruitment end date

2014-09-24, 1393/07/02

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A prospective randomized clinical trial on mid-cycle triggering of final oocyte maturation using GnRH versus HCG in Antagonist protocol

#### Public title

Comparing hormone profile and outcomes of ovulation triggering with GnRH and HGC in IVF

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: All patients who are candidate for IVF/ICSI( Male factor infertility, unexplained infertility,

tubal factor infertility), Age below 39 years old, BMI: 18-29, Regular menstrual cycles. Agreement of patient to enrol the research Exclusion criteria: Ovulatory factor infertility, Endometriosis, Uterine anomalies, Age above 39 years old, Non-agreement of patient to enrol the research

#### Age

From **24 years** old to **36 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **232**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Randomisation will be implemented using table of random numbers.

## Secondary Ids

### 1

#### Registry name

Shiraz University of Medical Sciences

#### Secondary trial Id

90-01-01-3979

#### Registration date

2012-09-10, 1391/06/20

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shiraz University of Medical Science

##### Street address

Shiraz University of Medical Science , Zand street

##### City

Shiraz

##### Postal code

#### Approval date

2013-02-21, 1391/12/03

#### Ethics committee reference number

CT-P-91-3979

## Health conditions studied

### 1

#### Description of health condition studied

Female infertility

#### ICD-10 code

N97.9

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Number and Quality of oocytes retrieved in each IVF cycle

#### Timepoint

on day of ovum pick up

#### Method of measurement

measuring number and quality of oocytes on the day of pick up by pathologist in lab under microscope and scoring.

### 2

#### Description

Progesterone level

#### Timepoint

on the day of injection HCG or GnRH agonist(Final Triggering) and rechecked 7 and 14 days after that

#### Method of measurement

Serum Level, Lab test

### 3

#### Description

Number and Quality of embryos transferred in IVF cycle

#### Timepoint

on day of embryo transfer

#### Method of measurement

measuring number and quality of embryos by pathologist in lab under microscope and grading.

### 4

#### Description

Comparing FSH, LH, Estradiol and HCG in both groups

#### Timepoint

on days 2 and 6 of menstrual cycle, final oocyte triggering, oocyte retrieval, 7 and 14 days after that oocyte retrieved

#### Method of measurement

Serum Level, Lab test

## Secondary outcomes

### 1

#### Description

Rate of ovarian hyperstimulation syndrome (OHSS)

**Timepoint**

From day of HCG or GnRH agonist injection up to 2 weeks later

**Method of measurement**

Clinical management of symptoms, Sonography

**2****Description**

Clinical Pregnancy

**Timepoint**

16 days after triggering if menstruation was absent

**Method of measurement**

Serum BHCG and TVS

**Intervention groups****1****Description**

Intervention group: In intervention group the patient will receive GnRh agonist (Decapeptyl; Ferring, The Netherlands), 0.2 mg sc for triggering final oocyte maturation

**Category**

Treatment - Drugs

**2****Description**

Control group: In control group the patients will receive HCG 10000 IU sc (Institute Biochimique SA (IBSA), The Switzerland) for triggering final oocyte maturation

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Madar-Koodak Hospital

**Full name of responsible person**

Dr. Leila Sarikhani

**Street address**

Entrance of Gulshan Town, Quran Gate

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor of Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Basir Hashemi

**Street address**

Shiraz University of Medical Sciences, Zand Street

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor of Research, Shiraz 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**

OB. & GYN Department, Shiraz Medical School

**Full name of responsible person**

Dr. leila Sarikhani

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Street

**City**

Shiraz

**Postal code****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*