

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparison of the effect of Follicle Stimulating Hormone(FSH) and Follicle Stimulating Hormone(FSH) along with growth hormone(GH) on ovulation stimulation in Intrauterine insemination (IUI) candidate patients and pregnancy outcomes

#### Protocol summary

##### Study aim

Comparison of the effect of FSH administration with FSH administration along with growth hormone in stimulation of ovulation in IUI candidate patients and pregnancy results

##### Design

After entering the study, patients will be divided into two groups: A (FSH) and group B (FSH plus growth hormone). Group A patients will receive FSH with a dose of 75 units on day 6 and 8 of cycle and group B, FSH in addition to 75 units of FSH on day 6 and 8 of cycle 3 units of growth hormone as a subcutaneous injection daily from day 2 of cycle to trigger day. For the trigger day, 5 thousand units of HCG ampoules are injected intramuscularly to both groups. And then 36 hours after the trigger day, IUI will be done and the results of IUI will be checked in both groups.

##### Settings and conduct

Infertility Clinic of Kawsar Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age between 25 and 35 years 2- Patients with at least one healthy fallopian tube 3- Normal spermogram 4- Regular menstrual cycle (26 to 30 days) 5- FSH level below 20 mIU/ml

##### Intervention groups

Group A patients will receive FSH with a dose of 75 units on day 6 and 8 of cycle and group B, FSH in addition to 75 units of FSH on day 6 and 8 of cycle 3 units of growth hormone as a subcutaneous injection daily from day 2 of cycle to trigger day.

##### Main outcome variables

Chemical pregnancy rate ,Clinical pregnancy rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230512058157N1**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

##### Registration date

2023-06-21, 1402/03/31

##### Registrant information

##### Name

Sonia Sadeghpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 5079

##### Email address

sadeghpour.s@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2024-10-21, 1403/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Follicle Stimulating Hormone(FSH) and Follicle Stimulating Hormone(FSH) along with growth hormone(GH) on ovulation stimulation in Intrauterine insemination (IUI) candidate patients and pregnancy outcomes

#### Public title

Comparison of the effect of FSH and FSH along with growth hormone on ovulation stimulation in IUI candidate patients and pregnancy outcomes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age between 25 and 35 years Patients with at least one healthy fallopian tube Normal spermogram Regular menstrual cycle (26 to 30 days) FSH level below 20 mIU/ml

##### Exclusion criteria:

#### Age

From **25 years** old to **35 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Patients will be divided randomly into two groups (A and B).The data collection form will be provided to the analyzer with the header A and B without mentioning the type of method performed on the patient. The results of the data analysis, will be provided to the analyst without mentioning the name of the method (group A and B) to examine the consequences.So, these people will be blinded.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

#### Street address

Kausar Women's Comprehensive Hospital

#### City

urmia

#### Province

West Azarbaijan

#### Postal code

5715859497

#### Approval date

2022-08-13, 1401/05/22

#### Ethics committee reference number

IR.UMSU.REC.1401.168

### Health conditions studied

#### 1

##### Description of health condition studied

infertility

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Antral follicle counts

##### Timepoint

before after treatment

##### Method of measurement

Sonography

#### 2

##### Description

serum level of FSH

##### Timepoint

before after treatment

##### Method of measurement

ELISA

#### 3

##### Description

Serum levels of insulin-like growth factor I (IGF-I)

##### Timepoint

before after treatment

##### Method of measurement

ELISA

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Follicle stimulating hormone along with growth hormone

**Category**

Treatment - Drugs

2**Description**

Control group: FSH

**Category**

Treatment - Drugs

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

Kowsar Hospital

**Full name of responsible person**

Dr.sonia sadeghpour

**Street address**

Hasani Blvd

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**Postal code**

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**Phone**

+98 21 3346 5079

**Email**

dr.sadehpour.s@gmail.com

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Saber Golizadeh

**Street address**

Jahad St., Resalat Blvd., Urmia University of Medical Sciences, Urmia, Iran

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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**

Oroumia University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr.Sonia Sadeghpour

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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Assistant Professor

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Subspecialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable