

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The Effect of Intrauterine Injection of Granulocyte Stimulant Factor on the Success of Intrauterine Sperm insemination in Patients Referred to Infertility Center of Ardabil University of Medical Sciences

#### Protocol summary

##### Study aim

The Effect of Intrauterine Injection of Granulocyte Stimulant Factor on the Success of Intrauterine Sperm insemination

##### Design

In this interventional study, 40 infertile women who met the inclusion criteria will be selected and divided into two groups using block randomization method (n=20 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

##### Settings and conduct

Both intervention and control groups will receive clomiphene (50 mg, daily, manufactured by Iran Hormone Pharmaceutical Company) from 3 to 7 days for 5 days. On the ninth day, an ultrasound will be performed. If the follicle is greater than or equal to 20 mm, in Fourteenth day 5,000 units of HCG (manufactured by Ronak Daru) will be given intramuscularly and will be administered IUI 36 hours later. In the intervention group, in addition to the previous actions on the day of IUI injection, 100 µg of G-CSF (Recpharma product) will be injected with the IUI catheter.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertility. Exclusion criteria: Endometriosis, Uterine Surgery History.

##### Intervention groups

Intervention group: Intrauterine injection of 100 µg G-CSF (Recpharma Co. product) and 36 hours later IUI. Control group: Perform IUI without intrauterine G-CSF injection.

##### Main outcome variables

Pregnancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191122045466N1**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **prospective**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

##### Registration date

2019-12-18, 1398/09/27

##### Registrant information

##### Name

elham mostafavi rad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3323 2232

##### Email address

e.mostafavirad@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of Intrauterine Injection of Granulocyte Stimulant Factor on the Success of Intrauterine Sperm insemination in Patients Referred to Infertility Center of Ardabil University of Medical Sciences

## Public title

The Effect of Intrauterine Injection of Granulocyte Stimulant Factor on the Success of Intrauterine Sperm insemination

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Infertility

### Exclusion criteria:

Endometriosis Uterine Surgery History

## Age

To **40 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Participants are not aware of the type of medication

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

##### Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

##### City

ARDABIL

## Province

Ardabil

## Postal code

5615783134

## Approval date

2019-08-29, 1398/06/07

## Ethics committee reference number

1398.286.IR.ARUMS.REC

## Health conditions studied

### 1

#### Description of health condition studied

Female infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Pregnancy

#### Timepoint

3 weeks after intervention

#### Method of measurement

Sonography

## Secondary outcomes

### 1

#### Description

Human chorionic gonadotropin hormone

#### Timepoint

Two weeks after intervention

#### Method of measurement

Laboratory

## Intervention groups

### 1

#### Description

Intervention group: Intrauterine injection of 100 µg G-CSF (Recpharma product) during IUI

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Perform IUI without intrauterine G-CSF injection

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alavi Hospital

**Full name of responsible person**

Elham Mostafavirad

**Street address**

Alavi Hospital, Moadi street, Ardabil

**City**

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**Postal code**

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+98 45 4233 8888

**Email**

e.mostafavirad@arums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Shahab.bohlooli

**Street address**

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

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s.bohlooli@pharmacy.arums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Elham Mostafavirad

**Position**

Gynecology Asisstant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Fariba Kahnamoee Agdam

**Position**

Gynecologist

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Elham Mostafavirad

**Position**

Gynecology Asisstant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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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**

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

**Statistical Analysis Plan**

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

**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**

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

**Data Dictionary**

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