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=20in 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
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Sponsors / Funding sources

1

Sponsor

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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
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
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Person responsible for updating data

Contact

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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