

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of intrauterine infusion of Granulocyte Colony-Stimulating Factor (G-CSF) on endometrial thickness in frozen embryo transfer

Protocol summary

Summary

Objectives: evaluating the effect of intrauterine infusion of Granulocyte colony-stimulating factor (G-CSF) on improvement endometrial thickness and improvement implantation rate and increasing pregnancy rate after transferring frozen embryo transfer in infertile women. Blinding: not blinding. Randomization: non-randomized. Study population : selecting 80 patients of infertile women admitting to infertile center of Ghadir child and mother hospital in shiraz after obtained informed consent and dividing them into two groups of 40 women (one group has women with endometrial thickness more than 6 mm as a control group, another group has women with endometrial thickness less than 6 mm as an intervention group). Inclusion criteria : Infertile women - Age between 20-45 - Patients are receiving estradiol valerate - women with endometrial thickness more than 6 mm and women with endometrial thickness less than 6 mm. Exclusion criteria: Presence of Granulocyte colony-stimulating factor (G-CSF) contra-indications including past history and presence of malignancy - History of uterine surgery - Renal failure - Azoospermia in patient's husband - Diabetes. Intervention : intrauterine injection of 300 microgram Granulocyte colony-stimulating factor (G-CSF) in tenth day of hormone replacement therapy (HRT cycle). Primary outcome : endometrial thickness. Secondary outcomes : implantation rate and clinical pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030722206N3**

Registration date: **2017-05-01, 1396/02/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name

Alamtaj Samsami

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research of Shiraz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrauterine infusion of Granulocyte Colony-Stimulating Factor (G-CSF) on endometrial thickness in frozen embryo transfer

Public title

The effect of Granulocyte Colony-Stimulating Factor (G-CSF) on endometrial thickness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women, Age between 20-45, women are receiving conventional treatment: estradiol valerate , women with normal endometrial thickness (more than 6 mm) for control group and women with endometrial thickness less than 6 mm for intervention group Exclusion criteria: Presence of Granulocyte colony stimulating factor (G-CSF) contra-indications including: Sickle cell anemia, Chronic neutropenia, Past history of malignancy, Presence of malignancy, Upper respiratory infections, History of uterine surgery, Renal failure, Azoospermia in patient's husband, Pneumonia, Congenital fructose intolerance, Thyroid diseases , Diabetes, Asherman syndrome

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not 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

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.SUMS.MED.REC.1395.04

Health conditions studied

1

Description of health condition studied

Infertility and treatment methods

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Before intervention and 72 hours after intervention

Method of measurement

Transvaginal sonography

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

3 weeks after positive serum β hCG

Method of measurement

Vaginal ultrasonography

2

Description

Implantation rate

Timepoint

14 days after embryo transfer

Method of measurement

Measurement of serum β hCG

Intervention groups

1

Description

Intervention group : intrauterine injection of 300 microgram Granulocyte colony-stimulating factor (G-CSF) in tenth day of hormone replacement therapy (HRT cycle)

Category

Treatment - Drugs

2

Description

Control group: not intrauterine injection of Granulocyte colony-stimulating factor (G-CSF), prescription of Estradiol valerate from second day of menstrual cycle and increasing dose (2 mg, every 4)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother & Child hospital

Full name of responsible person

Shima Talebi

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

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 for research of 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Shima Talebi

Position

Rezedent of Obstetrics & GYN

Other areas of specialty/work

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Other areas of specialty/work

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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