Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of granulocyte colony stimulating factor (G-CSF) on IVF outcome and pregnancy rates.

Protocol summary

Study aim
evaluating the effect of intrauterine infusion of G-CSF on pregnancy rate. study groups are infertile patients

Design
A clinical trial with the control group, with parallel groups, not blinded, phase 3 per 100 patients. A random number table was used for randomization.

Settings and conduct
This study is performed in Yazd Infertility Research Center. 100 IVF candidate patients are divided into 2 groups using a random table. One group receives the usual antagonist stimulation protocol. In the control group, in addition to the antagonist protocol, 300 micrograms of granulocyte colony-stimulating factor are infused into the endometrial cavity by intrauterine insemination catheter on the day of egg puncture.

Participants/Inclusion and exclusion criteria
inclusion : infertile women aged 18-40 years old with normal endometrial thickness who were candidates for IVF exclusion : Women with a history of repeated implantation failure , endocrine disorders, severe endometriosis, congenital or acquired uterine anomaly, renal disease, sickle cell disease, or malignancy history, upper respiratory tract infection, pneumonia, chronic neutropenia

Intervention groups
Intervention: injection of 300 micrograms G-CSF in the uterine cavity with IUI catheter in oocyte retrieval day control: oocyte retrieval will be done 36 hours after HCG triggering and embryos will be transferred 2 days latter.

Main outcome variables
chemical pregnancy, clinical pregnancy, Implantation rate, ongoing pregnancy , the miscarriage rate

General information

Reason for update
Updating exclusion criteria and outcomes according to the last methodological changes

Acronym

IRCT registration information
IRCT registration number: **IRCT201508236420N13**
Registration date: **2015-11-07, 1394/08/16**
Registration timing: **retrospective**

Last update: **2021-08-23, 1400/06/01**
Update count: **1**

Registration date
2015-11-07, 1394/08/16

Registrant information

Name
Maryam Eftekhar
Name of organization / entity
Yazd Research and Clinical Center for Infertility
Country
Iran (Islamic Republic of)
Phone
+98 35182470856
Email address
eftekhar@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Shahid Sadoughi University of Medical Science

Expected recruitment start date
2015-03-21, 1394/01/01

Expected recruitment end date
2015-09-23, 1394/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of granulocyte colony stimulating factor (G-CSF) on IVF outcome and pregnancy rates.

Public title
Effect of granulocyte colony stimulating factor in ART treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
infertile women candidate for IVF normal endometrial thickness age18-40 years old
Exclusion criteria:
repeated implantation failure endocrine disorders severe endometriosis congenital or acquired uterine anomaly renal disease sickle cell disease malignancy history upper respiratory tract infection pneumonia chronic neutropenia
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, infertile women who were scheduled for ART and met the inclusion criteria, informed about the research design and signed a written consent form for random assignment either to case or control groups. All women were randomly divided into two groups using simple, individual through random number table. All women were consecutively assigned into two groups based on randomized list.
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 Shahid Sadoughi University of Medical Science
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2015-02-08, 1393/11/19
Ethics committee reference number
444

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
serum βhCG

Secondary outcomes

1

Description
ongoing pregnancy
Timepoint
10 weeks after embryo transfer
Method of measurement
sonography

2

Description
abortion
Timepoint
18 weeks after embryo transfer
Method of measurement
sonography

3

Description
clinical pregnancy
Timepoint
3 weeks after positive BHCG
Method of measurement

sonography

4

Description
implantation
Timepoint
3 weeks after positive BHCG
Method of measurement
assessed by the number of gestational sacs per number of transferred embryos

Intervention groups

1

Description
In intervention group in oocyte retrieval day, 300 microgram G-CSF ampoul infused in endometrial cavity with IUI catheter immediately after retrieval.
Category
Treatment - Drugs

2

Description
in control group (50 patients) G-CSF not infused in endometrial cavity.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi University of Medical Science
Full name of responsible person
Dr.Maryam eftekhar, Associated Professor of Shahid Sadoughi University of medical science
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
98195999
Phone
+98 35 1824 7085
Email
eftekharmaryam@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Abass Aflatounian
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
98195999
Phone
+98 35 1824 7085
Email
eftekharmaryam@yahoo.com
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 Shahid Sadoughi 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
Sadoughi University of Medical Science ,Yazd
Full name of responsible person
Maryam Eftekhar
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085

Fax
+98 35 3824 7087
Email
eftekharmaryam@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sadoughi University of Medical Science
Full name of responsible person
Maryam Eftekhar
Position
Associated Professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
eftekharmaryam@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Maryam Eftekhar
Position
professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
eftekharmaryam@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participant data sets are to be shared
When the data will become available and for how long
2 months after the result publication
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
use in the retrospective study
From where data/document is obtainable
Yazd research and clinical center for infertility
What processes are involved for a request to access data/document
Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.
Comments