

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The comparing granulocyte colony stimulating factor , intra muscular and intra uterine form on fertilization at women with idiopathic infertility in intra uterine insemination.

Protocol summary

Study aim

The comparing granulocyte colony stimulating factor(GCSF) , subcutaneous and intrauterine form on fertilization at women with idiopathic infertility in intrauterine insemination(IUI).

Design

Randomized clinical trial with control and parallel group, double blind, Randomized, third phase , on 88 patients who divided in 4 groups of 22 Persons, randomized with a table of random numbers.

Settings and conduct

patients will randomly dividing two intervention groups of sub cutaneous and intrauterine injection of GCSF and two control group of intrauterine and sub cutaneous injection of placebo. Induction ovulation process will done and on trigger day patients will receive drug or placebo then IUI will done, after 2 weeks chemical pregnancy with lab data and after 4 weeks clinical pregnancy with sonography will assist. the person who injecting and collecting data and the person who analyze the data will blind.

Participants/Inclusion and exclusion criteria

Women with unexplained infertility between 20-38 year old without anatomical pelvic problems or endometriosis or male factor infertility

Intervention groups

Group received GCSF subcutaneous Group received GCSF intrauterine Group received placebo subcutaneous Group received placebo intrauterine

Main outcome variables

The main factor: endometrial thickness, chemical and clinical pregnancy will evaluate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046688N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

MARYAM Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 7001

Email address

faba_1366@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-05, 1398/01/16

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2019-04-05, 1398/01/16

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-03-18, 1398/12/28

Scientific title

The comparing granulocyte colony stimulating factor , intra muscular and intra uterine form on fertilization at

women with idiopathic infertility in intra uterine insemination.

Public title
Evaluation the effect of Granulocyte Colony Stimulating Factor on infertility

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Every patients with unexplained infertility
Exclusion criteria:
Pelvic anomaly Progressive endometriosis Azosperm sex partner Male factor infertility

Age
From **20 years** old to **38 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Actual sample size reached: **83**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study patients were divided in intrvention and control groups with a table of random numbers with individual units and with simple random method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study the person who injected the drug or placebo, the person who collecting data and the person who analyzing will blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of hormozgan university of medical sciences
Street address
Hormozgan university of medical sciences, shahid

chamran boulivard, bandarabbas

City
bandar abas

Province
Hormozgan

Postal code
7916613885

Approval date
2020-02-26, 1398/12/07

Ethics committee reference number
IR.HUMS.REC.1398.443

Health conditions studied

1

Description of health condition studied
infertility

ICD-10 code
N97.9

ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
chemical pregnancy, clinical pregnancy

Timepoint
beta hcg seum test 2 weeks after IUI, sonographic evaluation 4 weeks after IUI

Method of measurement
biochemical serum test, sonography and FHR observation

Secondary outcomes

1

Description
endometrial tickness

Timepoint
trigger day

Method of measurement
sonography

2

Description
chemical pregnancy

Timepoint
2 weeks after IUI

Method of measurement
laboratory test

3

Description
clinical pregnancy

Timepoint
4 weeks after IUI

Method of measurement

sonography

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Email

Maryamazizikut86@gmail.com

Intervention groups**1****Description**

Intervention group: sub cutaneous injection of 300 micro gram granulocyte with 0.5 milliliter in volume from Pooyesh Darou biopharmaceutical, made in iran in unique dose at trigger day

Category

Treatment - Drugs

2**Description**

Intervention group: intrauterine injection of 300 micro gram granulocyte with 0.5 milliliter in volume from Pooyesh Darou biopharmaceutical, made in iran in unique dose at trigger day

Category

Treatment - Drugs

3**Description**

Control group: 0.5 milliliter normal salin solution subcutaneous with unique dose on trigger day

Category

Placebo

4**Description**

Control group: 0.5 milliliter normal salin solution intrauterine with unique dose on trigger day

Category

Placebo

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

Infertility center of Hormozgan university of medical sciences

Full name of responsible person

Dr Maryam Azizi Cutenaei

Street address

Infertility center of Hormozgan university of medical sciences, 1st floor of Shafa burn center, pyambar azam convened, Parastar avenue

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Bandar abbas

Province

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Postal code

7916613885

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hormozgan university of medical sciences

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Chamran boulevard

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mail@hums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Azizi Cutenaei

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Infertility center of Hormozgan university of medical sciences, pyambar azam convened, parastar avenue, pyambar azam convened,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Full name of responsible person

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Position

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

results about fertility rate and association with BMI and endometrial thickness and ovarian reserve and injection method will participate

When the data will become available and for how long

start from winter 2020

To whom data/document is available

researchers working in educational institution

Under which criteria data/document could be used

adding up with other article

From where data/document is obtainable

dr maryam azizi, Maryamazizikut86@gmail.com

What processes are involved for a request to access data/document

The information will publish in an article at a creditable magazine after analyzing of data.

Comments