

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Frequency of fertility in unexplained male infertility referred to Urology clinic of Rafsanjan University of medical sciences after Human Menopausal Gonadotrophin (HMG) therapy

Protocol summary

Study aim

Determination of the frequency of fertility in unexplained infertile men following treatment with gonadotropin

Design

This clinical trial has a group of infertile men referred to the Urology Clinic will be select and enrolled to study by convenience method after informed consent.

Settings and conduct

Unexplained Infertile men referring to the Urology Clinic of the Rafsanjan University of Medical Sciences from the beginning of February 2019, will be enrolled in 30 individuals by convenience method after informed consent and HMG will be prescribed to them.

Participants/Inclusion and exclusion criteria

Unexplained Infertile men Age 25-40 years Without infertility in wife

Intervention groups

Intervention group: In this study, HMG is administered as an injectable intramuscular injection of 8 units per 75,000 units for a period of one month (2 injections per week).

Main outcome variables

Fertility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150317021497N5**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Mohammadreza Mokhtaree

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34260081

Email address

mrmmokhtaree@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Frequency of fertility in unexplained male infertility referred to Urology clinic of Rafsanjan University of medical sciences after Human Menopausal Gonadotrophin (HMG) therapy

Public title

Effect of Human Menopausal Gonadotrophin (HMG) therapy on fertility of infertile males

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

unexplained infertility 2 years since marriage Age 25-40 years Men

Exclusion criteria:
Wife Infertility

Age
From **25 years** old to **40 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali

City

Rafsanjan

Province

Kerman

Postal code

7713961151

Approval date

2018-03-01, 1396/12/10

Ethics committee reference number

IR.RUMS.REC.1396.125

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

frequency of fertility

Timepoint

3 months after beginning drug use

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 2 ampule of HMG (75000 unit) to 8 dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

urology Clinic, Rafsanjan University of medical sciences

Full name of responsible person

Alireza Nazari

Street address

Moradi hospital, Shohada ST

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Postal code

7713961151

Phone

+98 34 3426 0080

Email

mrmokhtaree@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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 7717933777
Phone
 +98 34 3428 0039
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 alishamsy@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 No
Title of funding source
 Personal
Proportion provided by this source
 1
Public or private sector
 Private
Domestic or foreign origin
 Domestic
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 Persons

Person responsible for general inquiries

Contact
Name of organization / entity
 Rafsanjan University of Medical Sciences
Full name of responsible person
 Alireza Nazari
Position
 Assistant professor
Latest degree
 Specialist
Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is 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

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 data can be shared after being unrecognizable.

When the data will become available and for how long

6 months after the end of the training

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

By providing a valid identification card and a letter of

introduction

From where data/document is obtainable

Mohammadreza Mokhtaree, mrmokhtaree@yahoo.com

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

After receiving the letter, it will be sent.

Comments