

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of changes in Gonadotropin Realizing Hormone (GnRH) injection time on intrauterine insemination in infertile women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of changes in Gonadotropin Realizing Hormone (GnRH) injection time on intrauterine insemination in infertile women

Design

This is a randomized clinical trial, phase II, in which 316 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible infertile women who will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 38 years Indication of intrauterine insemination Infertility for at least 10 years
Exclusion criteria: Non-visibility of the follicle in ultrasound or more than five cells Fallopian tube disorder History of abdominal and pelvic surgery Taking cytotoxic drugs

Intervention groups

Intervention group: Injection of Gonadotropin Realizing Hormone (GnRH) 0.2 mg and progesterone 50 mg intramuscular synchronized with intrauterine insemination Control group: Injection of Gonadotropin Realizing Hormone (GnRH) 0.2 mg and progesterone 50 mg intramuscular 36 to 40 hours before intrauterine insemination

Main outcome variables

The success of intrauterine insemination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N287**

Registration date: **2019-07-01, 1398/04/10**

Registration timing: **prospective**

Last update: **2019-07-01, 1398/04/10**

Update count: **0**

Registration date

2019-07-01, 1398/04/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-06, 1398/04/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of changes in Gonadotropin Realizing Hormone

(GnRH) injection time on intrauterine insemination in infertile women: a randomized clinical trial

Public title
Effect of changes in Gonadotropin Releasing Hormone (GnRH) injection time on intrauterine insemination in infertile women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 38 years Indication of intrauterine insemination Infertility for at least 10 years
Exclusion criteria:
Non-visibility of the follicle in ultrasound or more than five cells Fallopian tube disorder History of abdominal and pelvic surgery Taking cytotoxic drugs

Age
From **18 years** old to **38 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **316**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-06-15, 1398/03/25
Ethics committee reference number
IR.UMSHA.REC.1398.253

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

The success of intrauterine insemination

Timepoint

2 weeks after the intervention

Method of measurement

By seeing embryo through ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of Gonadotropin Releasing Hormone (GnRH) 0.2 mg and progesterone 50 mg intramuscular synchronized with intrauterine insemination

Category

Treatment - Drugs

2

Description

Control group: Injection of Gonadotropin Releasing Hormone (GnRH) 0.2 mg and progesterone 50 mg intramuscular 36 to 40 hours before intrauterine insemination

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan City

Full name of responsible person

Dr. Marzieh Farimani

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

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Postal code

6517838695

Phone

+98 81 3828 3939

Email

dr_farimani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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**

Iran University of Medical Sciences

Full name of responsible person

Dr. Marzieh Farimani

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Marzieh Farimani

Position

Gynecologist

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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