Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of synchronized injection versus routine injection of human chorionic gonadotropin (HCG) on intrauterine insemination (IUI) in infertile women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of synchronized injection versus routine injection of human chorionic gonadotropin (HCG) on intrauterine insemination (IUI) in infertile women

Design
This is a randomized clinical trial, phase II, in which 248 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 human chorionic gonadotropin (HCG) 1500 U intramuscular synchronized with intrauterine insemination (IUI) Control group: Injection of human chorionic gonadotropin (HCG) 1500 U intramuscular 36 to 40 hours before intrauterine insemination (IUI)

Main outcome variables
Primary outcome: The success of intrauterine insemination

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20120215009014N286**
Registration date: **2019-06-29, 1398/04/08**
Registration timing: **prospective**

Last update: **2019-06-29, 1398/04/08**
Update count: **0**

Registration date
2019-06-29, 1398/04/08

Registrant information
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Jalal Poorolajal
Name of organization / entity
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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 synchronized injection versus routine injection

of human chorionic gonadotropin (HCG) on intrauterine insemination (IUI) in infertile women: a randomized clinical trial

Public title
Effect of synchronized injection versus routine injection of human chorionic gonadotropin (HCG) on intrauterine insemination (IUI) 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
3
Groups that have been masked
No information
Sample size
Target sample size: **248**
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.1398.219

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 human chorionic gonadotropin (HCG) 1500 U intramuscular synchronized with intrauterine insemination (IUI)
Category
Treatment - Drugs

2

Description
Control group: Injection of human chorionic gonadotropin (HCG) 1500 U intramuscular 36 to 40 hours before intrauterine insemination (IUI)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital in Hamadan City

Full name of responsible person
Dr. Roghayeh Anvari Aliabadi

Street address
Fatemieh Hospital, Pasdaran Ave.

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Hamadan

Province
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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
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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
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Roghayeh Anvari Aliabadi

Position
Gynecologist

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person
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Position
Professor of Epidemiology

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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