Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of subcutaneous injection of hCG versus intrauterine injection before freeze embryo transfer

Protocol summary

Study aim
This study aims to compare the effect of intrauterine injection of human chorionic gonadotropin (hCG) with its subcutaneous injection before frozen embryo transfer on clinical pregnancy rate, embryo implantation rate, and other pregnancy outcomes.

Design
Randomized clinical trial with parallel groups, single-blind design, and sample size of 150 participants (50 in each group). Randomization will be performed using block randomization method with Excel software.

Settings and conduct
This study will be conducted at the Infertility Center of Ardabil University of Medical Sciences. Patients in all three groups will undergo standard protocols for embryo transfer preparation. Blinding will be applied only to patients.

Participants/Inclusion and exclusion criteria
Women aged 20-40 years with infertility; candidates for frozen embryo transfer; having at least one good quality embryo; FSH less than 10 mIU/ml. Exclusion criteria: structural uterine abnormalities; severe chronic diseases; more than three previous unsuccessful treatment cycles.

Intervention groups
Group 1: Subcutaneous injection of 1500 IU hCG on embryo transfer day; Group 2: Intrauterine injection of 500 IU hCG before embryo transfer; Group 3 (control): Embryo transfer without hCG injection.

Main outcome variables
Clinical pregnancy (presence of gestational sac in ultrasound); embryo implantation rate; live birth rate; miscarriage rate; endometrial thickness and pattern; serum levels of hCG and progesterone; injection side effects.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250307064956N1**
Registration date: **2025-05-08, 1404/02/18**
Registration timing: **prospective**

Last update: **2025-05-08, 1404/02/18**
Update count: **0**

Registration date
2025-05-08, 1404/02/18

Registrant information

Name
Elahe Shabanalizade

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-22, 1404/03/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the efficacy of subcutaneous injection of hCG versus intrauterine injection before freeze embryo transfer

Public title
Effect of hCG injection on frozen embryo transfer success
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 20 to 40 years Women with primary or secondary infertility who are candidates for frozen embryo transfer Having at least one frozen embryo of suitable quality for transfer FSH level less than 10 mIU/ml on the third day of the period Anti-Müllerian hormone (AMH) more than 1.1 ng/ml Couples using their own gametes Patients with good ovarian response
Exclusion criteria:
Structural abnormalities of the uterus or severe endometriosis affecting embryo implantation Severe chronic diseases such as uncontrolled diabetes or severe cardiovascular diseases Use of medications that interfere with human chorionic gonadotropin Having more than three previous unsuccessful treatment cycles using assisted reproductive techniques Unwillingness or inability to follow treatment protocols and scheduled timelines
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization will be performed using the random blocking method. Participants, after being informed and obtaining informed consent, will be randomly assigned to one of three study groups (subcutaneous hCG injection group, intrauterine hCG injection group, and control group). Randomization will be carried out using Excel software with the RAND BETWEEN function by the researcher. Random blocking will be used to ensure an equal number of participants in each group. Specific codes will be generated for each participant, and the intervention received will be marked through these confidential codes (which only the researcher and the supervisor know). Blinding will only be applied to patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, only the participants (patients) are blinded to the type of intervention they receive. Patients will not be informed about their group assignment or the type of injection they receive (subcutaneous human chorionic gonadotropin injection, intrauterine human chorionic gonadotropin injection, or control group). The researcher and the treatment team will be aware of the allocation. Specific codes will be generated for each participant, and the type of intervention received will be recorded through these confidential codes (which only the researcher and the supervisor know) to ensure that patients remain unaware of their group assignment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ardabil University of Medical Sciences
Street address
Ardabil: Daneshgah Street, Daneshgah Square, North Side of the Administrative Complex of Ardabil University of Medical Sciences, Vice Chancellor for Research and Technology of the Universit
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Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.ARUMS.REC.1403.465

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Clinical pregnancy (presence of intrauterine gestational sac in ultrasound)
Timepoint
Five weeks after embryo transfer (fifth week of pregnancy)
Method of measurement
Transvaginal ultrasound for observation and confirmation

of intrauterine gestational sac

Secondary outcomes

1

Description
Embryo implantation rate
Timepoint
Two weeks after embryo transfer
Method of measurement
Blood test for beta-hCG and confirmation with transvaginal ultrasound

2

Description
Live birth
Timepoint
After completion of pregnancy
Method of measurement
Observation and documentation of live birth

3

Description
Endometrial thickness and pattern (trilaminar pattern)
Timepoint
On the day of embryo transfer
Method of measurement
Transvaginal ultrasound

4

Description
Serum levels of human chorionic gonadotropin and progesterone
Timepoint
On the day of embryo transfer and days afterward
Method of measurement
Blood test

5

Description
Injection site adverse effects
Timepoint
Immediately after injection and in subsequent visits
Method of measurement
Clinical examination and patient report

Intervention groups

1

Description
Intervention group 1: Subcutaneous injection of human chorionic gonadotropin (hCG). In this group, 1500 IU of hCG will be injected subcutaneously on the day of embryo transfer. After endometrial preparation with standard protocols (agonist or antagonist), frozen embryo transfer will be performed. Patients will be followed up for clinical pregnancy 5 weeks after embryo transfer.
Category
Treatment - Drugs

2

Description
Intervention group 2: Intrauterine injection of human chorionic gonadotropin (hCG). In this group, 500 IU of hCG will be injected into the uterine cavity before embryo transfer. After endometrial preparation with standard protocols (agonist or antagonist), frozen embryo transfer will be performed. Patients will be followed up for clinical pregnancy 5 weeks after embryo transfer.
Category
Treatment - Drugs

3

Description
Control group: Frozen embryo transfer without human chorionic gonadotropin (hCG) injection. In this group, after endometrial preparation with standard protocols (agonist or antagonist), frozen embryo transfer will be performed without hCG injection. Patients will be followed up for clinical pregnancy 5 weeks after embryo transfer.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Infertility Treatment Center (ART), Alavi Hospital
Full name of responsible person
Tiba Mirzarahimi
Street address
Specialized Infertility Treatment Center, Alavi Educational and Medical Center, Shahid Moadi Street, Ayatollah Moghaddas Ardabili Street, Ardabil
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Daneshgah Street, Daneshgah Square, Northern Side of the Administrative Complex of Ardabil University of Medical Sciences, Vice Chancellor for Research and Technology
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Grant name
Vice Chancellor for Research and Technology of Ardabil University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
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Full name of responsible person
Elahe Shabanalizadeh
Position
Resident
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Person responsible for updating data

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Latest degree
Medical doctor
Other areas of specialty/work
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elahe_shabanalizade@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data confidentiality
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable