

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the effect of intrauterine injection of human chorionic gonadotropin (hCG) on pregnancy outcomes in the transfer of fresh embryos in cycles related to assisted reproductive technology (ART)

Protocol summary

Study aim

The effect of intrauterine injection of hCG on pregnancy outcomes in the transfer of fresh embryos

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 158 patients. Random Allocation Software (RAS) is used for randomization.

Settings and conduct

Referred to the Shariati Hospital in Tehran in 2023; selection of 158 patients based on inclusion and exclusion criteria; randomization into two intervention and control groups by Random Allocation Software; blinding of patients

Participants/Inclusion and exclusion criteria

Inclusion: Aged 20 to 39 years old; embryos with A and B quality and fresh embryo transfer. Exclusion: Transfer of frozen embryo, age more than 40 years, male infertility, history of myomectomy, presence of hydrosalpinx, presence of fibroids with pressure effect on endometrium and endometriosis.

Intervention groups

Intervention group: On the day of transfer of a fresh embryo, injection of 500 units of hCG into the uterus with a cook transfer catheter, daily reception of one progesterone suppository every 12 hours, and daily injection of one progesterone ampoule for two weeks, checking serum beta-hCG level two weeks after the initial injection of hCG, vaginal ultrasound and observation of the patient's gestational sac 2 weeks after the positive pregnancy test. Control group: On the day of transfer of a fresh embryo, injection of 500 units of hCG into the uterus with a cook transfer catheter, daily reception of one progesterone suppository every 12 hours, and a daily injection of one progesterone ampoule for two weeks, checking serum beta-hCG level two weeks after the initial injection of hCG, vaginal ultrasound and observation of the patient's gestational sac 2 weeks after

the positive pregnancy test.

Main outcome variables

Embryo implantation rate; clinical pregnancy rate; abortion rate MR; ongoing pregnancy rate (OPR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230803059016N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

bahareh ghahroudizadeh abyaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 3039

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-27, 1402/06/05

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of intrauterine injection of human chorionic gonadotropin (hCG) on pregnancy outcomes in the transfer of fresh embryos in cycles related to assisted reproductive technology (ART)

Public title
Investigating the effect of intrauterine injection of human chorionic gonadotropin (hCG) on pregnancy outcomes in the transfer of fresh embryos in cycles related to assisted reproductive technology (ART)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20 to 39 years old Embryos with A and B quality and fresh embryo transfer
Exclusion criteria:
 Transfer of frozen embryo Male infertility History of myomectomy Presence of hydrosalpinx Presence of fibroids with pressure effect on endometrium and endometriosis. Age more than 40 years

Age
From **20 years** old to **39 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **158**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 158 patients will be randomly divided into two intervention groups (79 patients, HCG injection) and a placebo group (79 patients, standard treatment) by assigning three-digit codes by Random Allocation Software (RAS). Allocation concealment is used for concealment. This is done using opaque sealed envelopes in a random sequence (numbered, sealed, opaque envelopes). In this method, each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lids of the envelopes are glued and put in the box. At the time of registration of the participants, based on the order of arrival of the eligible participants, the envelopes will be opened and the assigned group of that participant will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description

The blinding of this study will be single-blind and the patients will not be informed about the placement of individuals in the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Tehran University of Medical Sciences
Street address
 6th floor of Research and Technology Deputy, Central Organization of the University, corner of Quds St, Keshavarz Blvd., Tehran
City
 Tehran
Province
 Tehran
Postal code
 1411713135

Approval date
2023-06-26, 1402/04/05

Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.052

Health conditions studied

1

Description of health condition studied
Pregnancy

ICD-10 code
Pregnancy

ICD-10 code description
O00-O08

Primary outcomes

1

Description
Embryo implantation rate

Timepoint
Before and after the intervention

Method of measurement
Vaginal ultrasound

Secondary outcomes

1

Description

Clinical pregnancy rate

Timepoint

Before and after the intervention

Method of measurement

Vaginal ultrasound

2

Description

Abortion rate MR

Timepoint

Before and after the intervention

Method of measurement

Vaginal ultrasound

3

Description

Ongoing pregnancy rate (OPR)

Timepoint

Before and after the intervention

Method of measurement

Vaginal ultrasound

Intervention groups

1

Description

Intervention group: After the completion of puncture, on the day of transfer of a fresh embryo with A-B cleavage stage, injection of 500 units of hCG (volume 0.1 cc, manufactured by Aburihan company) into the uterus with a cook transfer catheter, daily reception of one progesterone suppository every 12 hours (manufactured by Aburihan company) for 2 weeks, daily injection of one progesterone ampoule for 2 weeks (manufactured by Aburihan company), checking serum beta-hCG level two weeks after the initial injection of hCG to evaluate the positive or negative pregnancy, vaginal ultrasound and observation of the patient's gestational sac 2 weeks after the positive pregnancy test (4 weeks after the initial hCG injection).

Category

Treatment - Drugs

2

Description

Control group: After the completion of puncture, on the day of transfer of a fresh embryo with A-B cleavage stage, injection of 500 units of hCG (volume 0.1 cc, manufactured by Aburihan company) into the uterus with a cook transfer catheter, daily reception of one progesterone suppository every 12 hours (manufactured by Aburihan company) for 2 weeks, daily injection of one progesterone ampoule for 2 weeks (manufactured by Aburihan company), checking serum beta-hCG level two weeks after the initial injection of hCG to evaluate the positive or negative pregnancy, vaginal ultrasound and

observation of the patient's gestational sac 2 weeks after the positive pregnancy test (4 weeks after the initial the peripheral solution).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Sedigheh Hosseinimousa

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Shariati hospital, in front of the Faculty of Economics, North Kargar St., Jalal Al-Ahmed Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Behareh Ghahroudzadeh Abianeh
Position
Obstetrics and Gynecology Resident
Latest degree
Medical doctor
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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The person's information will be confidential and the results will be as collective statistics.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be a research article and its results report and statistical analysis will be published to be used by therapists and researchers.

When the data will become available and for how long

If the journal has requested access to the data at any time, the data will be provided.

To whom data/document is available

Journal Editor and Reviewers

Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

From where data/document is obtainable

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

Mail to sedighehoseinimosa@gmail.com
Comments