Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intrauterine infusion of human chorionic gonadotropin and cultural environment of hyaluronan acid (embryo glue) on pregnancy outcomes in women with recurrent implantation failure

Protocol summary

Study aim
Effect of human chorionic gonadotropin and hyaluronan acid culture medium (embryo glue) in infertile women.

Design
A controlled, single blind, randomized phase 2 clinical trial on 158 patients. Randomization: Patients are divided into intervention and control groups randomly by using the block randomization method, and just the analyst will be blinded.

Settings and conduct
In Infertility Treatment Center of Imam Khomeini Hospital in Sari, for all eligible patients, endometrial preparation was performed according to the treatment protocol, and procedure of intervention will be explained to all patients. Then patients were randomly divided into two intervention and control groups using the block randomization method and after the intervention and follow-up of the outcomes, the data will be sent to the analyst as the results of two groups (A and B), and thus the analyst will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infertile women in frozen-thawed embryo transfer cycle and with grade A and B embryos; Exclusion criteria: Presence of uterine abnormalities, uncontrolled endocrine disease

Intervention groups
Intervention group: the group for which intrauterine infusion of HCG and embryo glue will be used. In this group, 20 minutes before embryo transfer, 500 units of HCG and 15 microliters of embryo culture medium (stage one stop origin) by catheter embryo transfer is loaded into the uterus guided by abdominal ultrasound. after 20 minutes the embryos are transferred into the embryo transfer catheter and are transferred into the uterus guided by abdominal ultrasound. Control group: The group for which routine infertility treatment protocols will be used.

Main outcome variables
Implantation, abortion, chemical, clinical and ongoing pregnancy,

General information

Reason for update
The sample size was increased to 158 people in order to increase the value of the study and refer to it.

Acronym

IRCT registration information
IRCT registration number: **IRCT20221126056614N1**
Registration date: **2023-02-22, 1401/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-30, 1403/05/09**
Update count: **1**

Registration date
2023-02-22, 1401/12/03

Registrant information

Name
Pegah Jafarifard

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-06, 1401/09/15

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of intrauterine infusion of human chorionic gonadotropin and cultural environment of hyaluronan acid (embryo glue) on pregnancy outcomes in women with recurrent implantation failure

Public title
Effect of human chorionic gonadotropin and embryo glue in infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women who have a history of at least 3 failed transfer cycles or failed transfer of 4 good quality (grade A or B) embryos. Women who are in the frozen-thawed embryo transfer cycle and their preparation is done using estrogen and progesterone. Women who have at least one grade A or B embryo on the day of embryo transfer
Exclusion criteria:
Donated oocyte Donated embryo Surrogacy Presence of hydrosalpinx in hysterosalpingography or ultrasound History of uncontrolled endocrine diseases: diabetes, hypothyroidism and hyperthyroidism Male factor infertility (azoospermia) Difficult embryo transfer (needs manipulation of the cervix or under anesthesia) Uterine abnormalities Presence of severe endometriosis and endometrioma
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **158**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups with equal size using the random block method of 4 people, which is done by the Randomize Allocate software and using their admission row number.
Blinding (investigator's opinion)
Single blinded
Blinding description
Regarding the method of blinding, after conducting the intervention and following up the outcomes, the data will be sent to the analyst in the form of results in two groups (A and B), in this way, the analyst does not know which patients are in the intervention group and which patients are in the control group, and the study will be single blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini Hospital, Mazandaran University of Medical Sciences
Street address
Imam Khomeini Hospital, Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2022-10-18, 1401/07/26
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1401.038

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98
ICD-10 code description
Complications associated with artificial fertilization

Primary outcomes

1

Description
Rate of Implantation
Timepoint
5 weeks after intervention
Method of measurement
Ultrasound

2

Description
Rate of Abortion
Timepoint
18 weeks after intervention
Method of measurement
Fetus excretion

3

Description
Rate of chemical pregnancy
Timepoint
3-4 weeks after intervention
Method of measurement
Pregnancy test

4

Description
Rate of clinical pregnancy
Timepoint
5 weeks after intervention
Method of measurement
Ultrasound

5

Description
Ongoing pregnancy
Timepoint
38 weeks after intervention
Method of measurement
Delivery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intrauterine infusion of human chorionic gonadotropin and embryo glue. In this group, 20 minutes before embryo transfer, 500 units of HCG (Pharmed Daru) and 15 microliters of embryo culture medium (stage one stop origin) were loaded into the uterus by the embryo transfer catheter guided by abdominal ultrasound. after 20 minutes, the embryos are transferred into the embryo transfer catheter and are transferred into the uterus under the guidance of abdominal ultrasound.
Category
Treatment - Drugs

2

Description
Control group: In the control group, the embryos are transferred into the culture medium without the use of HCG and hyaluronic acid and then transferred into the uterine cavity.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Sepideh Peivandi
Street address
Imam Khomeini hospital, Amir Mazandarani Ave
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4816633131
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnezhad
Street address
Research and Technology Deputy Building, Moalem Square
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Fax
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Sepideh Peivandi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Medical doctor

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The protocol and method of conducting the study can be provided to researchers for use in other studies.

When the data will become available and for how long
The access period starts 2 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used
For use in other studies

From where data/document is obtainable
Postal address: Imam Khomeini Hospital, Amir Mazandarani Ave, Sari. Email address: Pegahjafarifard.m.d@icloud.com Phone number: 0098 9127372572

What processes are involved for a request to access data/document
With sending Email and in one week

Comments