

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The pregnancy success rate after frozen embryo transfer with and without intrauterine injection of HCG-activated peripheral blood mononuclear cells in infertile women: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the pregnancy success rate after frozen embryo transfer with and without intrauterine injection of HCG-activated peripheral blood mononuclear cells in infertile women

Design

This is a single-blind randomized clinical trial, in which 92 eligible infertile women 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 block randomization. This trial will be single-blinded so that patients will not be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years, Female infertility, Having healthy uterine, Having two high-quality fetuses for transfer, History of at least three times failure of IVF-ET Exclusion criteria: Male infertility, Endocrine diseases, Diabetes

Intervention groups

Intervention group: Transfer of frozen embryos plus an intrauterine injection of 20 ml centrifuged and activated HCG from 20 ml peripheral blood Control group: Transfer of frozen embryos alone

Main outcome variables

Primary outcome: Serum β HCG level Pregnancy sac

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N308**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **prospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The pregnancy success rate after frozen embryo transfer

with and without intrauterine injection of HCG-activated peripheral blood mononuclear cells in infertile women: a single-blind randomized clinical trial		Ethics Committee of Hamadan University of Medical Sciences	
Public title The pregnancy success rate after frozen embryo transfer with and without intrauterine injection of HCG-activated peripheral blood mononuclear cells in infertile women		Street address Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave	
Purpose Treatment		City Hamadan	
Inclusion/Exclusion criteria Inclusion criteria: Age of 18 to 35 years, Female infertility, Having healthy uterine, Having two high-quality fetuses for transfer, History of at least three times failure of IVF-ET Exclusion criteria: Male infertility, Endocrine diseases, Diabetes		Province Hamadan	
Age From 18 years old to 35 years old		Postal code 6517838695	
Gender Female		Approval date 2019-09-15, 1398/06/24	
Phase N/A		Ethics committee reference number IR.UMSHA.REC.1398.461	
Groups that have been masked Participant		Health conditions studied 1 Description of health condition studied Female infertility ICD-10 code N97 ICD-10 code description Female infertility	
Sample size Target sample size: 92		Primary outcomes 1 Description Serum β HCG level Timepoint 14 days after the intervention Method of measurement Through laboratory test	
Randomization (investigator's opinion) Randomized		2 Description Pregnancy sac Timepoint 28 days after intervention Method of measurement By using ultrasonography	
Randomization description The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.		Secondary outcomes empty	
Blinding (investigator's opinion) Single blinded		Intervention groups 1 Description Intervention group: Transfer of frozen embryos plus an intrauterine injection of 20 ml centrifuged and activated HCG from 20 ml peripheral blood Category Treatment - Drugs	
Blinding description The patients will be unaware of the type of intervention. Thus, the trial will be run as single-blind			
Placebo Not used			
Assignment Parallel			
Other design features			
Secondary Ids empty			
Ethics committees 1 Ethics committee Name of ethics committee			

2

Description

Control group: Transfer of frozen embryos alone

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan City

Full name of responsible person

Dr. Nages Sajedi

Street address

Fatemieh Hospital, Pasdaran Ave.

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Province

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6517838695

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fahimesalarii67@gmail.com

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. Nages Sajedi

Position

Resident of Gynecology

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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Latest degree

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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