

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

Country

Iran (Islamic Republic of)

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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		Province	Hamadan
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	Postal code	6517838695
Exclusion criteria:	Male infertility, Endocrine diseases, Diabetes	Approval date	2019-09-15, 1398/06/24
Age	From 18 years old to 35 years old	Ethics committee reference number	IR.UMSHA.REC.1398.461
Gender	Female	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	Participant	Description of health condition studied	
Sample size	Target sample size: 92	Female infertility	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
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.	N97	
Blinding (investigator's opinion)	Single blinded	ICD-10 code description	
Blinding description	The patients will be unaware of the type of intervention. Thus, the trial will be run as single-blind	Female infertility	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	Serum β HCG level	
Ethics committees		Timepoint	
1		14 days after the intervention	
Ethics committee		Method of measurement	
Name of ethics committee		Through laboratory test	
		2	
		Description	
		Pregnancy sac	
		Timepoint	
		28 days after intervention	
		Method of measurement	
		By using ultrasonography	
		Secondary outcomes	
		empty	
		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	

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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.

City

Hamadan

Province

Hamadan

Postal code

6517838695

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+98 81 3828 3939

Email

fahimesalarii67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

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Medical doctor

Other areas of specialty/work

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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