

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of infertility treatment with and without addition of autologous platelet-rich plasma in embryo transfer in patients candidate for intra cytoplasmic sperm injection: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of infertility treatment with and without addition of autologous platelet-rich plasma in embryo transfer in patients candidate for intra cytoplasmic sperm injection

Design

This is a randomized clinical trial, phase II, in which 56 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients candidate for intra cytoplasmic sperm injection who will refer to Fatemieh Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 40 years; Candidate for embryo transfer; Having at least two embryos of good quality to transfer; Having a healthy uterus cavity
Exclusion criteria: Patients in need of sperm donation; Patients in need of ovum donation; Previous history of embryo transfer; Endocrine diseases such as hyperthyroidism, hypothyroidism, hyperprolactinemia, diabetes

Intervention groups

Intervention group: Routine infertility treatment plus injection of autologous platelet-rich plasma 20% once
Control group: Just routine infertility treatment

Main outcome variables

Primary outcome: Chemical pregnancy Clinical pregnancy Seeing fetal heart sonography Secondary outcome: Abortion

General information

Reason for update

This study was implemented later than the time predicted in the project. The only place that needs to change is the start and end time of the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N230**

Registration date: **2018-08-24, 1397/06/02**

Registration timing: **prospective**

Last update: **2024-11-20, 1403/08/30**

Update count: **1**

Registration date

2018-08-24, 1397/06/02

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of infertility treatment with and without addition of autologous platelet-rich plasma in embryo transfer in patients candidate for intra cytoplasmic sperm injection: a randomized clinical trial

Public title

Effect of infertility treatment with and without addition of autologous platelet-rich plasma in embryo transfer in patients candidate for intra cytoplasmic sperm injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 20 to 40 years; Candidate for embryo transfer; Having at least two embryos of good quality to transfer; Having a healthy uterus cavity

Exclusion criteria:

Patients in need of sperm donation; Patients in need of ovum donation; Previous history of embryo transfer; Endocrine diseases such as hyperthyroidism, hypothyroidism, hyperprolactinemia, diabetes

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.UMSHA.REC.1397.235

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 days after intervention

Method of measurement

Through laboratory test

2

Description

Clinical pregnancy

Timepoint

21 days after intervention

Method of measurement

By sonography

3

Description

Seeing fetal heart

Timepoint

28 days after intervention

Method of measurement

By sonography

Secondary outcomes

1

Description

Abortion

Timepoint

28 days after intervention

Method of measurement

Through history taking

Intervention groups

1

Description

Intervention group: Routine infertility treatment plus injection of autologous platelet-rich plasma 20% once

Category

Treatment - Drugs

2

Description

Control group: Just routine infertility treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Fahimeh Salari Shahre Babaki

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

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

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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 Fahimeh Salari Shahre Babaki

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

fahimesalarii67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Marzieh Sanooei Farimani

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
dr_farimani@yahoo.com

Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan

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