Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Jalal Poorolajal
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Fahimeh Salari Shahre Babaki
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Resident of Gynecology
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Person responsible for updating data

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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