

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of intrauterine injection effects of PRP (platelet-rich plasma) and Hams F10 on the pregnancy outcome in recurrent implantation failure of infertile women after transferring unfrozen embryo

Protocol summary

2017-04-08, 1396/01/19

Summary

Objectives: To compare the effect of platelet-rich plasma versus Hams F10 on the pregnancy outcome in infertile women with recurrent implantation failure after transferring unfrozen embryo. Design: a single blind randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 20 to 42 years; implantation failure for at least 3 times. Exclusion criteria: pregnancy contraindication; weak response to gonadotropin; presence of any type of chronic disease such as anemia or endocrine disorders or renal failure. Intervention group: Intrauterine injection of 0.5 to 1 ml platelet-rich plasma 24 to 36 hours before implantation. Control group: Intrauterine injection of 0.5 to 1 ml Hams F10, 24 to 36 hours before implantation. Primary outcome: (a) Assessing pregnancy with β hCG 2 weeks after intervention; (b) assessing pregnancy with ultrasonography 4 weeks after intervention. Secondary outcome: Nothing. Randomization: Random assignment of the patients to the intervention and control groups. Blinding: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017033133179N1**
Registration date: **2017-04-08, 1396/01/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Nasrin Azami Fard

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3525 0182

Email address

itc@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-10-29, 1395/08/08

Expected recruitment end date

2017-04-28, 1396/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intrauterine injection effects of PRP (platelet-rich plasma) and Hams F10 on the pregnancy outcome in recurrent implantation failure of infertile women after transferring unfrozen embryo

Public title

Comparison of intrauterine injection effects of PRP (platelet-rich plasma) and Hams F10 on the pregnancy outcome in recurrent implantation failure of infertile

women after transferring unfrozen embryo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 20 to 42 years; implantation failure for at least 3 times. Exclusion criteria: pregnancy contraindication; weak response to gonadotropin; presence of any type of chronic disease such as anemia or endocrine disorders or renal failure.

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: Here block randomization technique is used. For this purpose we provide 4 paper sheets and on two papers, letter "I" (intervention) is written and on another two papers letter "P" (placebo). Then papers are mixed once and are put in the drawer. After visiting a candidate, one of the papers is given to her whether "I" or "P". By this method candidates are allocating in intervention or placebo group randomly. Blinding: Here only researchers but not the subjects know which subjects are receiving the treatment, therefore it is a single blind study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Khajeh Rashid Cross, Ayatollah Kashani Blv

City

Hamadan

Postal code

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.UMSHA.REC.1395.342

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Assessing pregnancy

Timepoint

2 weeks after intervention

Method of measurement

with β hCG

Secondary outcomes

1

Description

Assessing pregnancy

Timepoint

4 weeks after intervention

Method of measurement

with ultrasonography

Intervention groups

1

Description

Intrauterine injection of 0.5 to 1 ml platelet-rich plasma
24 to 36 hours before implantation

Category

Treatment - Drugs

2

Description

Intrauterine injection of 0.5 to 1 ml Hams F10 24 to 36
hours before implantation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital, Hamadan

Full name of responsible person

Dr Nasrin Azami Fard

Street address

Fatemieh Hospital, Pasdaran Ave. Hamadan
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Nasrin Azami Fard

Position

Gynecology resident

Other areas of specialty/work

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code

Phone

+98 81 3821 9905

Fax

Email

nazami51@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Marzieh Farimani

Position

Gynecologist

Other areas of specialty/work

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code

Phone

+98 81 3828 3939

Fax

Email

dr_farimani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Nasrin Azami Fard

Position

Gynecology resident

Other areas of specialty/work

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code

Phone

+98 81 3821 9905

Fax

Email

nazami51@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty