

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of routine treatment with and without intravenous immunoglobulin (IVIG) on Th17 and Th1:Th2 and CD56+16+ serum levels in patients with repeated unexplained in vitro fertilization failure: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of routine treatment with and without intravenous immunoglobulin (IVIG) on Th17 and Th1:Th2 and CD56+16+ serum levels in patients with repeated unexplained in vitro fertilization failure

Design

This a randomized clinical trial, phase II, in which 42 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients repeated unexplained in vitro fertilization failure who will refer to Fetemieh Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 35 years Repeated unexplained in vitro fertilization failure Exclusion criteria: Anatomical abnormalities of the uterus Endocrine disorder Genetic disorder Infectious diseases

Intervention groups

Intervention group: Routine treatment plus intravenous immunoglobulin single dose before embryo transfer
Control group: Just routine treatment

Main outcome variables

Primary outcome: Measuring Th17 before intervention and two weeks after that through laboratory test
Measuring Th1:Th2 before intervention and two weeks after that through laboratory test
Measuring CD56+16+ before intervention and two weeks after that through laboratory test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N217**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **retrospective**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

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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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of routine treatment with and without intravenous

immunoglobulin (IVIG) on Th17 and Th1:Th2 and CD56+16+ serum levels in patients with repeated unexplained in vitro fertilization failure: a randomized clinical trial

Public title
Effect of routine treatment with and without intravenous immunoglobulin (IVIG) on fertility induction in patients with repeated unexplained in vitro fertilization failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 35 years Repeated unexplained in vitro fertilization failure
Exclusion criteria:
Anatomical abnormalities of the uterus Endocrine disorder Genetic disorder Infectious diseases

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to the intervention and control groups by random sequencing method, in which 21 patients will be assigned to the intervention group and 21 patients will be assigned to the control group.

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

2017-03-04, 1395/12/14

Ethics committee reference number

IR.UMSHA.REC.1395.580

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Measuring Th17

Timepoint

Before intervention and two weeks after that

Method of measurement

Through laboratory test

2

Description

Measuring Th1:Th2

Timepoint

Before intervention and two weeks after that

Method of measurement

Through laboratory test

3

Description

Measuring CD56+16+

Timepoint

Before intervention and two weeks after that

Method of measurement

Through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus intravenous immunoglobulin prepared from fresh plasma 400 mg/kg just single dose before embryo transfer

Category

Treatment - Drugs

2

Description

Control group: Just routine treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Tayebbeh Artimani

Street address

Fatemieh Hospital, Pasdaran Ave.

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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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Hamadan University of Medical Sciences, Shahid
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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 Tayebbeh Artimani

Position

Reproduction Biology Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Tayebbeh Artimani

Position

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Person responsible for updating data

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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

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Email

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