

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Immunomodulatory Effects of Hydroxychloroquine on immunological factors involved in implantation of women with repeated implantation failure: clinical trial

Protocol summary

Summary

This study was designed to evaluate the effectiveness of Hydroxychloroquine on implantation. This clinical trial is performed in Infertility and IVF word, Shahid Motahari hospital. 30 infertile patients with a history of at least three repeated implantation failure or immune system disorders (impaired T helper 1/ T helper 2 balance) are recruited into the study. Patients were treated with 400 mg Hydroxychloroquine daily for 16 days. The treatment was started from day 3 or 4 of the menstrual cycle and at the 19-20th day of the cycle, the endometrial samples were obtained. In fact, the sampling was performed twice: once before the treatment and again after the treatment. Then, each endometrial sample was divided into two parts to examine the cytokines involved in the implantation by immunohistochemistry and their related genes by polymerase chain reaction (PCR).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060634209N1**

Registration date: **2017-07-13, 1396/04/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-13, 1396/04/22

Registrant information

Name

Hojjat Ghasemnejad berenji

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 340 7313

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immunomodulatory Effects of Hydroxychloroquine on immunological factors involved in implantation of women with repeated implantation failure: clinical trial

Public title

Effect of Hydroxychloroquine in patients with repeated implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients having an immunological disorder in serum (Tumor necrosis factor alpha/Interleukin-10 $\geq$ 30.6); 3 failed embryo transfer
Exclusion criteria: uterine abnormality (acquired or congenital); unwillingness to continue

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences

Street addressShahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway**City**

Tehran

Postal code**Approval date**

2017-05-30, 1396/03/09

Ethics committee reference number

IR.SBMU. MSP.REC.1396.160

Health conditions studied**1****Description of health condition studied**

Repeated Implantation Failure

ICD-10 code

N-97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes**1****Description**

Interleukin -10

Timepoint

Twice: before and after intervention

Method of measurement

Immunohistochemistry

2**Description**

Tumor necrosis factor alfa

Timepoint

Twice: before and after intervention

Method of measurement

Immunohistochemistry

3**Description**

Interleukin-17

Timepoint

Twice: before and after intervention

Method of measurement

Immunohistochemistry

4**Description**

GATA3 gene

Timepoint

Twice: before and after intervention

Method of measurement

Polymerase chain reaction

5**Description**

Interleukin-4

Timepoint

Twice: before and after intervention

Method of measurement

Immunohistochemistry

6**Description**

T-bet gene

Timepoint

Twice: before and after intervention

Method of measurement

Polymerase chain reaction

7**Description**

FOXP-3 gene

Timepoint

Twice: before and after intervention

Method of measurement

Polymerase chain reaction

8**Description**

RORyt gene

Timepoint

Twice: before and after intervention

Method of measurement

Polymerase chain reaction

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer in next cycle

Method of measurement

Serum BHCG

Intervention groups

1

Description

Women receive oral Hydroxychloroquine (400 mg/day) for 16 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and IVF ward of Shahid Motahari hospital

Full name of responsible person

00984433197713

Street address

Kashani Blvd Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

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Shahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway

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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

Shahid Beheshti 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

Urmia University of Medical Sciences

Full name of responsible person

Dr.Sonia Sadeghpour

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Professor

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Full name of responsible person

Dr.Hojjat Ghasemnejad Berenji

Position
Other areas of specialty/work
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Phone
00
Fax
Email
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