Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 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

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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>= 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 address
Shahid 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
RORγt 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
Street address
Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway
City
Tehran
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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Hojjat Ghasemnejad Berenji

Position
Other areas of specialty/work
Street address
City
Postal code
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