# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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)

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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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Assistant professor
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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**Full name of responsible person**
Dr.Hojjat Ghasemnejad Berenji

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00
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**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*