

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Assessment the effect of hydroxychloroquine on the treatment of unexplained recurrent abortion in women referred to Arash hospital

#### Protocol summary

##### Summary

The aim of this study is to assess the effect of hydroxychloroquine on unexplained recurrent abortion. This clinical trial would be conducted as a prospective and double blind survey. Inclusion criteria is women with at least 2 unexplained recurrent abortion and exclusion criteria is women with lupus and underlying diseases. Our sample size is 60. After getting informed consent of participants, they will be randomly divided into two groups of intervention and control. After positive pregnancy test, the intervention group will receive 200 mg hydroxychloroquine 2 times a day up to the twentieth gestational week, and control group will receive placebo as the same way of intervention group. Patients would be monitored by sonography in 6-8, 11-13 and 18-22 of gestational weeks and outcomes of pregnancy and its complications will be assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120910664N2**

Registration date: **2016-07-18, 1395/04/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-18, 1395/04/28

##### Registrant information

##### Name

Reihaneh Pirjani

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 3288

##### Email address

pirjani@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Experimental Medicine Research Center of Tehran University of Medical Science

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2017-12-22, 1396/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the effect of hydroxychloroquine on the treatment of unexplained recurrent abortion in women referred to Arash hospital

##### Public title

Effect of hydroxychloroquine on recurrent abortion treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria : women with more than 2 unexplained abortion  
exclusion criteria: women with rheumatoid; lupus erythematosus; underlying and heart diseases; smoking; consumption of alcohol and supplement; radiation contact

##### Age

From **18 years** old to **45 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Science

##### Street address

Tehran University of Medical Science, Qods Street, Keshavarz Boulevard

##### City

Tehran

##### Postal code

#### Approval date

2016-06-26, 1395/04/06

#### Ethics committee reference number

IR.TUMS.REC.1395.2743

## Health conditions studied

### 1

#### Description of health condition studied

recurrent abortion

#### ICD-10 code

O03

#### ICD-10 code description

Spontaneous abortion

## Primary outcomes

### 1

#### Description

spontaneous abortion

#### Timepoint

any time during study

#### Method of measurement

observational

## Secondary outcomes

### 1

#### Description

Intrauterine death

#### Timepoint

after 20 weeks of gestation

#### Method of measurement

observational

### 2

#### Description

preeclampsia

#### Timepoint

all the duration of pregnancy

#### Method of measurement

clinical and laboratory examination

### 3

#### Description

low birth weight

#### Timepoint

after birth

#### Method of measurement

weighing

### 4

#### Description

preterm labor

#### Timepoint

before 37 th week of gestation

#### Method of measurement

observational

### 5

#### Description

congenital morphological abnormalities

#### Timepoint

after birth

#### Method of measurement

observational

## Intervention groups

### 1

#### Description

intervention group: After confirming the positive pregnancy test, patients will receive tablet of 200 mg hydroxychloroquine twice a day up to the twentieth week of pregnancy. Sonography will be done in weeks of 6-8, 11-13 and 18-22 of pregnancy.

#### Category

Treatment - Drugs

### 2

#### Description

control group: After confirming the positive pregnancy test, patients will receive placebo twice a day up to the twentieth week of pregnancy. Sonography will be done in weeks of 6-8, 11-13 and 18-22 of pregnancy.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Arash women hospital

**Full name of responsible person**

Dr.Reihaneh Pirjani

**Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Experimental Medicine Research Center of Tehran  
University of Medical Science, Vice chancellor for res

**Full name of responsible person**

Dr Masoud Younesian

**Street address**

Tehran University of Medical Science, Keshavarz  
boulevard, Qods street,

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Experimental Medicine Research Center of Tehran  
University of Medical Science, Vice chancellor for res

**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**

Arash Women 's Hospital, Tehran University of  
Medical sciences

**Full name of responsible person**

Dr. Reihaneh Pirjani

**Position**

Associated professor

**Other areas of specialty/work****Street address**

Arash women hospital, Rashid street, Tehranpars

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Highway, Tehranparse

**City**

Tehran

**Postal code****Phone**

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**Fax****Email**

**Web page address**

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## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*