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

Thje 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 tow 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 complicationes 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

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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 Centerof 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 Centerof 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

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

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Phone

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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