Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of spiramycin in prevention of toxoplasma gondii infection from mothers with acute toxoplasmosis

Protocol summary

Study aim
This study is aimed to evaluate the efficacy of spiramycin in prevention of toxoplasma gondii transmission from mother with acute toxoplasmosis.

Design
This study will be a single arm clinical trial and recruit 50 individuals in 10 years. With respect to the nature of the study no randomization will be performed.

Settings and conduct
This clinical study will be performed in teaching hospitals of Babol University of Medical Sciences. All pregnant women with acute toxoplasmosis will be included in this study and treated with drugs until delivery, thereafter, their offspring will be followed for a year. With respect to the nature of the study no blinding or randomization will be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria includes, informed consent and having positive or borderline IgM and positive IgG antibodies against Toxoplasma gondii. Exclusion criteria includes, having high avidity test, negative IgM antibodies against Toxoplasma gondii or positive fetal anomaly screening tests.

Intervention groups
Pregnant women with acute toxoplasmosis infection will receive 1gr of spiramycin every 8 hours until delivery.

Main outcome variables
Prevalence of Toxoplasma gondii infection in children delivered from mothers with acute toxoplasmosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170201032346N5**
Registration date: **2020-12-26, 1399/10/06**
Registration timing: **retrospective**
Last update: **2020-12-26, 1399/10/06**
Update count: **0**

Registration date
2020-12-26, 1399/10/06

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 91155226108
Email address
firoozihosein@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2007-09-23, 1386/07/01

Expected recruitment end date
2011-09-23, 1390/07/01

Actual recruitment start date
2007-09-23, 1386/07/01

Actual recruitment end date
2016-09-22, 1395/07/01

Trial completion date
2018-07-23, 1397/05/01

Scientific title
The effect of spiramycin in prevention of toxoplasma gondii infection from mothers with acute toxoplasmosis

Public title
The effect of spiramycin in prevention of toxoplasma infection in neonates

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Positive Anti-Toxoplasma gondii IgG and IgM antibodies

Signed informed consent

Exclusion criteria:

High positive avidity test Negative Anti-Toxoplasma gondii IgM antibodies Positive screening tests for fetal anomalies

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Not randomized

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice Chancellor of Research, Moalem st, Moalem sq, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.MAZUMS.REC.1395.2690

Health conditions studied

1

Description of health condition studied

Congenital Toxoplasmosis

ICD-10 code

P37.1

ICD-10 code description

Congenital toxoplasmosis

Primary outcomes

1

Description

Prevalence of congenital toxoplasmosis

Timepoint

Evaluation of infant until a year after birth

Method of measurement

Physical examination and performing diagnostic tests based on patient complaint

2

Description

Fetal abortion

Timepoint

from diagnosis and initiation of treatment until delivery

Method of measurement

History, physical examination and sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mothers will be treated with 1gr of spiramycin every 8 hours until delivery and their offspring will be followed for a year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Yahyanezad Hospital

Full name of responsible person

Hossein Firoozi

Street address

Shahid Mostafa Khomeini St.

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3222 3594

Email

firoozihosein@mazums.ac.ir

2

Recruitment center
Name of recruitment center
Babol 17 Shahrivar Hospital
Full name of responsible person
Hossein Firoozi
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4716681451
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3

Recruitment center
Name of recruitment center
Babol Ayatollah Rouhani Hospital
Full name of responsible person
Hossein Firoozi
Street address
Ganj Afrooz St.
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47117647745
Phone
+98 11 3223 8301
Email
firoozihosein@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ramsar Campus, Mazandaran University of Medical Sciences
Full name of responsible person
Davood Farzin
Street address
No.20 ,Taleghani Ave., Ramsar.
City
Ramsar
Province
Mazandaran
Postal code
4691786953
Phone
+98 11 5522 6108
Email
firoozihosein@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ramsar Campus, Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Firouzi Hossein
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No.20 ,Taleghani Ave., Ramsar.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Web page address

Person responsible for updating data

Contact

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Mazandaran University of Medical Sciences

Full name of responsible person

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Subspecialist

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+1 155230181

Fax

Email

firoozihosein@mazums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified data for primary and secondary outcome measures are going to be shared.

When the data will become available and for how long

After publishing the study, data are going to be available

To whom data/document is available

data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

requests are gathered through principle researcher's e-mail address

What processes are involved for a request to access data/document

requests are gathered through principle researcher's e-mail address

Comments