

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the effects of topical povidone iodine (2.5%), and topical erythromycin in prevention of ophthalmia neonatorum, in Shiraz, in 2014

Protocol summary

Summary

1. Objective: The objective is to define the effectiveness of povidone iodine and erythromycin and find the most effective and economical method for prevention of ophthalmia neonatorum. 2. Design: In a masked randomized clinical trial 2100 neonates are randomly divided to three groups of Erythromycin (E), povidone iodine (P) and control groups. According to Iranian healthy newborn care service package, which is the guideline for Iranian pediatricians for newborn care, if mothers had no gonococcal or chlamydial infections, prophylaxis is not recommended for ophthalmia neonatorum. Mothers are educated about the signs of ophthalmia neonatorum. All cases will be visited on 3 occasions: After 24 hours, days 3-7 and days 7-10. 3. Setting and conduct: In a 2 month period in 2 major hospitals of Hafez and Zeynabieh in Shiraz. 4. Participants and eligibility criteria: All neonates with maternal consent and inclusion criteria and not having the following exclusion criteria: ocular malformations, antibiotic usage by mother in the last week of pregnancy, mothers can't bring the neonate to hospital in case of conjunctivitis, and mothers with current gonococcal or chlamydial infection. each group has 700 enrollees (n=700); as a result, 2100 neonates will be studied. 5. Intervention: Subjects are randomly assigned to Erythromycin (E), povidone iodine (P) and control groups. 6. Main outcome: Presence or absence of ophthalmia neonatorum.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031717034N1**

Registration date: **2014-04-19, 1393/01/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Homeira Vafaei Cisakht

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

vafaeih@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research deputy of Shiraz university of medical sciences, Infertility Research Center, Shiraz university of medical sciences.

Expected recruitment start date

2014-04-05, 1393/01/16

Expected recruitment end date

2014-07-07, 1393/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of topical povidone iodine (2.5%), and topical erythromycin in prevention of ophthalmia neonatorum, in Shiraz, in 2014

Public title

Povidone iodine and topical erythromycin in prevention

of ophthalmia neonatorum

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: mother's consent. Exclusion criteria: Ocular malformations; Antibiotic usage by mother in the last week of pregnancy; Mothers can't bring the neonate to hospital in case of conjunctivitis; Mothers with current gonococcal or chlamydial infection.

Age

To **1 month** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **2100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences ethics committee

Street address

Shiraz university of medical sciences, Zand blvd.

City

Shiraz

Postal code

Approval date

2014-02-23, 1392/12/04

Ethics committee reference number

CT-P-92-5107

Health conditions studied

1

Description of health condition studied

Neonatal chlamydial conjunctivitis and neonatal conjunctivitis NOS.

ICD-10 code

P39.1

ICD-10 code description

Neonatal chlamydial conjunctivitis. Ophthalmia neonatorum NOS.

2

Description of health condition studied

Neonatal gonococcal conjunctivitis.

ICD-10 code

A54.3.

ICD-10 code description

Gonococcal conjunctivitis.

Primary outcomes

1

Description

Presence or absence of conjunctivitis

Timepoint

3 Occasions: After 24 hours, days 3-7 and days 7-10

Method of measurement

History and physical exam

Secondary outcomes

1

Description

Cultured microorganism

Timepoint

When conjunctivitis detected

Method of measurement

Culture

Intervention groups

1

Description

Neonates with no eye abnormalities or infection are divided to two groups. Group 1 receives topical erythromycin at the time of birth. At first 24 hours, 3-7 and 7-10 days later patients are visited for infection.

Category

Prevention

2

Description

Neonates with no eye abnormalities or infection are divided to two groups. Group 2 receives topical povidone iodine at the time of birth. At first 24 hours, 3-7 and 7-10 days later patients are visited for infection.

Category

Prevention

3

Description

Neonates with no eye abnormalities or infection are

divided to two groups. Group 3 (control) receives distilled water at the time of birth. At first 24 hours, 3-7 and 7-10 days later patients are visited for infection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

dr Nasrin dadras

Street address

Chamran Blvd.

City

Shiraz

2

Recruitment center

Name of recruitment center

Hazrate Zeinab hospital

Full name of responsible person

dr Nasrin Dadras

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research of Shiraz university of medical sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

7th Floor dean of research, Shiraz university of medical sciences, Zand blvd

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor of research of Shiraz 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

Shiraz university of medical sciences

Full name of responsible person

Hossein Haghbin

Position

Medical intern

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Homeira Vafaei Cisakht

Position

Assistant Professor, Fellowship of perinatology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shiraz university of medical sciences

Full name of responsible person

Khadije Bazrafshan

Position

Masters

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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