

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Clinical Trial: Comparison, effect of Ophthalmic ointment tetracycline1% and erythromycin 0.5% in prophylaxis of ophthalmia Neonatorum.

Protocol summary

Summary

Aim: Comparison, effect of ophthalmic ointment tetracycline1% and erythromycin 0.5% in prophylaxis of ophthalmia Neonatorum. Type of Study: Monocentric Single blind random controlled clinical trial without placebo The study group included neonates that born in Sanandaj Besat Hospital from march 2010 to march 2011. They were born both normal vaginal delivery and cesarean section. Inclusion criteria was normal neonates without congenital ophthalmic anomalies whom their mother had not received any antibiotics 48 hours before delivery and had not history of PROM (during 18 hrs to delivery) and meconium aspiration. Method: 330 neonates divided in 3 equal groups, 1 hour after birth after primary care and breast milk feeding. In group A one cm of ophthalmic ointment Tetracycline 1% and in group B one cm of ophthalmic ointment Erythromycin 0.5% was applied in both eyes. Group C was the control without medication. Questionnaire has 2 parts. The first part filled by nurse or Pediatrics Resident in the post partum ward. Before discharge the signs of conjunctivitis like redness, eye swelling and purulent discharge discussed for mothers and recommended them to come back on end of first and second and 4th weeks of birth every day. They was visited in OPD of Besat hospital. If they didn't come, we contacted them by telephone. If the infant had the any symptoms of conjunctivitis they was visited urgently and the second part of questionnaire including type of eye in comfort was filled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101295714N1**

Registration date: **2011-02-27, 1389/12/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-27, 1389/12/08

Registrant information

Name

Mohammad Hossein Kalantar

Name of organization / entity

Kurdistan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kordestan University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial: Comparison, effect of Ophthalmic ointment tetracycline1% and erythromycin 0.5% in prophylaxis of ophthalmia Neonatorum.

Public title

Comparison, effect of Ophthalmic ointment tetracycline1% and erythromycin 0.5% in prophylaxis of

ophthalmia Neonatorum.

Purpose
Prevention

Inclusion/Exclusion criteria
The study group included neonates that born in Sanandaj Besat Hospital from march 2010 to march 2011. They were born both normal vaginal delivery and cesarean section. An inclusion criterion was neonates born in Besat hospital. Exclusion criteria was congenital ophthalmic anomalies; receiving any antibiotics 48 hours before delivery; history of PROM (during 18 hrs to delivery); and meconium aspiration

Age
To 1 year old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 330

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Science Ethics Committee

Street address

Kurdistan University of Medical Science, Pasdaran AV., sanandaj

City

Sanandaj

Postal code

6618634683

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

82226

Health conditions studied

1

Description of health condition studied

neonatal conjunctivitis

ICD-10 code

P39.1

ICD-10 code description

Neonatal conjunctivitis

2

Description of health condition studied

Gonococcal conjunctivitis

ICD-10 code

A54.3

ICD-10 code description

Gonococcal infection of eye

Primary outcomes

1

Description

neonatal conjunctivitis

Timepoint

before intervention, 1 week, 2 weeks and 4 weeks later

Method of measurement

clinical examination

Secondary outcomes

1

Description

allergic reaction

Timepoint

1, 2, and 4 weeks after intervention

Method of measurement

clinical examination

Intervention groups

1

Description

330 neonates divided in 3 equal groups. In group A one cm of ophthalmic ointment Tetracyclin 1% was applied in both eyes just one time 1 hour after birth.

Category

Prevention

2

Description

In group B one cm of ophthalmic ointment Erythromycin 0.5% was applied in both eyes just one time 1 hour after birth.

Category

Treatment - Drugs

3

Description

Group C was the control without medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mohammad Hossein Kalantar

Street address

Besat Hospital, Keshavarz Av., Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Sciences Vice chancellor for research, Kordistan

Full name of responsible person

Ataollah Heidari

Street address

Medical University of Kordistan Vice Chancellor for Research, Pasdaran Av., Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Medical Sciences Vice chancellor for research, Kordistan

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

Kurdistan University of Medical Science

Full name of responsible person

Mohammad Hossein Kalantar

Position

Doctor/ Pediatrics Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Science

Full name of responsible person

Nahid Ghotbi

Position

Professor

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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