Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of 2.5% betadine in the prevention of neonatal conjunctivitis

Protocol summary

Summary

The aim of this study was to evaluate the effect of Betadine 2.5% on prevention of neonatal conjunctivitis. Inclusion criteria will be included all healthy term and preterm neonates. Exclusion criteria will be included all neonates that need for resuscitation, special measures and neonates with congenital malformations of the eyes. The statistical population of this study will be included all neonates those will bear from September 23, 2017 to March 20, 2018 in Qazvin Kowsar Hospital. The sample number will be 200 neonates. In the first group, two drops of Betadine 2.5% (prophylaxis group) and the second group two drops of distilled sterile water (control group) will be shed in the conjunctiva of the eyes. Intervention will be only taken place on the first day of birth. The primary outcome variables will be included eye redness, purulent discharge and inflammation of conjunctive of eyes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022032680N1**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name

Fakhrosadat Hosseini Moghaddam Emami

Name of organization / entity

Qazvin university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 8709

Email address

f.emami@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin university of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 2.5% betadine in the prevention of neonatal conjunctivitis

Public title

The effect of betadine drop in neonatal conjunctivitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All healthy term and preterm neonates
Exclusion criteria: All neonates that needs to resuscitation; special measures; neonates with congenital malformations of the eyes

Age

To **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of medical Sciences

Street address

Bahonar Blvd, Qazvin University of Medical Sciences, Qazvin

City

Qazvin

Postal code

59811-34197

Approval date

2017-01-25, 1395/11/06

Ethics committee reference number

IR.QUMS.REC.1395.280

Health conditions studied

1

Description of health condition studied

Neonatal Conjunctivitis

ICD-10 code

P39.1

ICD-10 code description

Neonatal conjunctivitis and dacryocystitis

Primary outcomes

1

Description

Conjunctivitis

Timepoint

22 May 2017-23 June 2017

Method of measurement

Visual

Secondary outcomes

1

Description

Drug sensitivity

Timepoint

48 hours and one week after treatment

Method of measurement

Visual

Intervention groups

1

Description

In the second group (control) two drops of distilled sterile water will be shed in the conjunctiva eyes

Category

Prevention

2

Description

In the first group (Intervention), two drops of Betadine 2.5% will be shed in the conjunctiva eyes

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital, Qazvin University of Medical Sciences

Full name of responsible person

Fakhrosadat Hosseini Moghaddam Emami

Street address

Kosar Hospital, Kosar Alley, Taleqani St., Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences, Qazvin

Full name of responsible person

Amir Peymani

Street address

Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences, Qazvin

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
Qazvin University of Medical Sciences
Full name of responsible person
Fakhrosadat Hosseini Moghaddam Emami
Position
General practitioner
Other areas of specialty/work
Street address
Qazvn University of Medical Sciences, Bahonar Blvd, Qazvin
City
Qazvin
Postal code
59811-34197
Phone
+98 28 3333 6001
Fax
+98 28 3333 6002
Email
f.emami@qums.ac.ir
Web page address
http://www.qums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fakhrosadat Hosseini Moghaddam Emami
Position
General practitioner
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin
City
Qazvin
Postal code
59811-34197
Phone
+98 28 3333 6001
Fax
+98 28 3333 7006
Email
f.emami@qums.ac.ir
Web page address
http://www.qums.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fakhrosadat Hosseini Moghaddam Emami
Position
General practitioner
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin
City
Qazvin
Postal code
4595-1-34159
Phone
+98 28 3333 6001
Fax
+98 28 3333 7006
Email
f.emami@qums.ac.ir
Web page address
http://www.qums.ac.ir/

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