

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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*

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## 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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Web page address**  
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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*