

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Investigating the role of educating and follow up by discharge nurse on retinopathy prevention in neonates admitted to neonatal intensive care unit of shahid beheshti hospital in kashan at 2018

#### Protocol summary

##### Study aim

Determining the role of educating and follow up by discharge nurse on retinopathy prevention in neonates admitted to neonatal intensive care unit

##### Design

Quasi-experimental study with control group

##### Settings and conduct

60 eligible mothers with premature newborns who were referred to neonatal intensive care unit of Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: parental consent for participation in the research; gestational age less than 37 weeks. Exclusion criteria: parental unwillingness to participate in the continuation of the project; baby's feet.

##### Intervention groups

Intervention group: Pre-discharge teaching, screening of premature infants in terms of ROP, telephone follow-up of post-discharge visual examinations, and caregivers education about the necessary care before eye examinations. Control group: hospital's routine program was implemented included some teaching pamphlet and giving the referral form to the ROP clinic and the neonate discharge summary sheet at the time of discharge to the parents.

##### Main outcome variables

The number of visit the ophthalmologists to prevent retinopathy; relative frequency of retinopathy.

#### General information

##### Reason for update

##### Acronym

ROP

##### IRCT registration information

IRCT registration number: **IRCT20180506039545N1**

Registration date: **2018-05-24, 1397/03/03**

Registration timing: **prospective**

Last update: **2018-05-24, 1397/03/03**

Update count: **0**

##### Registration date

2018-05-24, 1397/03/03

##### Registrant information

###### Name

Amir Ahmadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7527

###### Email address

amir.ahmadi@nmmail.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-31, 1397/03/10

##### Expected recruitment end date

2018-10-02, 1397/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the role of educating and follow up by discharge nurse on retinopathy prevention in neonates admitted to neonatal intensive care unit of shahid

beheshti hospital in kashan at 2018

## Public title

Investigating the role of educating and follow up by discharge nurse on retinopathy prevention in neonates

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Parental consent for participation in the research  
Gestational age more than 32 and less than 37 weeks  
Birth weight less than 2,000 gr

### Exclusion criteria:

Parental unwillingness to participate in the continuation of the project  
Baby's feet Absence, cooperation and participation in eye examination sessions (up to 2 consecutive sessions)  
The impossibility of making phone calls with the caregiver of the infant with ROP at a given time  
The absence of the parent or the caregiver of the infant in the training sessions during hospitalization or during discharge  
Neonates' discharge before the end of study

## Age

From **1 day** old to **28 days** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Not 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

Ethics Committee of Isfahan University Medical sciences

##### Street address

Pediatric and Neonatal Department, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Avenue, Darvazeh Shiraz, Isfahan, Iran

##### City

Isfahan

## Province

Isfahan

## Postal code

81746-73461

## Approval date

2018-04-06, 1397/01/17

## Ethics committee reference number

IR.MUI.REC.1397.3.001

## Health conditions studied

### 1

#### Description of health condition studied

Retinopathy

#### ICD-10 code

P07.17

#### ICD-10 code description

Other low birth weight newborn, 1750-1999 grams

## Primary outcomes

### 1

#### Description

The number of visit the ophthalmologists to prevent retinopathy

#### Timepoint

At the end of the fourth month after the intervention

#### Method of measurement

Checklist

### 2

#### Description

Relative frequency of retinopathy

#### Timepoint

At the end of the fourth month after the intervention

#### Method of measurement

Checklist

### 3

#### Description

Stage and region of retinopathy involvement

#### Timepoint

At the end of the fourth month after the intervention

#### Method of measurement

Checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: pre-discharge teaching, screening of premature infants in terms of ROP, telephone follow-up of post-discharge visual examinations, and caregivers

education about the necessary care before eye examinations

**Category**

Prevention

2

**Description**

Control group: hospital's routine program was implemented included some teaching pamphlet and giving the referral form to the ROP clinic and the neonate discharge summary sheet at the time of discharge to the parents.

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti hospital

**Full name of responsible person**

Mehran Sharifi

**Street address**

The Neonatal Intensive Care Unit, Shahid beheshti hospital, Pezeshk Blvd, 5th of Qotb-e Ravandi, Kashan city, Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

87159-1151

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amir.ahmadi@nmmail.mui.ac.ir

**Web page address**

http://beheshti.kaums.ac.ir/

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy-Javanmard

**Street address**

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Hezarjarib Street

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Ahmadi

**Position**

Student of Master of Science in Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Pediatric and Neonatal Department, School of Nursing and Midwifery, Esfahan University of Medical Sciences, Hezar Jerib Avenue, Darvazeh Shiraz, Isfahan, Iran

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sedigheh Talakoub

**Position**

Master of Science in Nursing, Member of Academic

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sedigheh Talakoub

**Position**

Master of Science in Nursing, Member of Academic

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable