Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Amir Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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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
Isfehan
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy-Javanmard

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

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Web page address

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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

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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
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Latest degree
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Nursery

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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