

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oral vitamin A versus control group in the prevention of retinopathy of prematurity in low birth weight neonates: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral vitamin A versus control group in the prevention of retinopathy of prematurity in low birth weight neonates

Design

This is a double-blind randomized clinical trial, phase III, in which 66 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible low birth weight premature neonate referring to the Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than a month; Neonate with birth weight less than 1500 g; Premature neonate with gestational age less than 34 weeks; Exclusion criteria: Congenital malformations; Heart disease or any background disease

Intervention groups

Intervention group: Routine care including surfactant 5 ml/kg daily and injection of Ampicillin 25 mg/kg every 12 hours and Amikacin 7.5 mg/kg every 12 hours for one week plus oral drop vitamin A 3000 U (manufactured by Hamadan School of Pharmacy) per neonate weight daily for 28 days Control group: Just routine care including surfactant 5 ml/kg daily and injection of Ampicillin 25 mg/kg every 12 hours and Amikacin 7.5 mg/kg every 12 hours for one week

Main outcome variables

Primary outcome: Retinopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N403**

Registration date: **2021-08-21, 1400/05/30**

Registration timing: **prospective**

Last update: **2021-08-21, 1400/05/30**

Update count: **0**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral vitamin A versus control group in the prevention of retinopathy of prematurity in low birth weight neonates: a double-blind randomized clinical trial

Public title

Effect of oral vitamin A versus control group in the prevention of retinopathy of prematurity in low birth weight neonates

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than a month; Neonate with birth weight less than 1500 g; Premature neonate with gestational age less than 34 weeks;

Exclusion criteria:

Congenital malformations; Heart disease or any background disease

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on three sheets the name of the intervention and on the other three sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are infants and thus will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.UMSHA.REC.1400.312

Health conditions studied**1****Description of health condition studied**

Retinopathy

ICD-10 code

H35.109

ICD-10 code description

Retinopathy of prematurity, unspecified, unspecified eye

Primary outcomes**1****Description**

Retinopathy

Timepoint

Before the intervention and one month later

Method of measurement

Through physical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Routine care including surfactant 5 ml/kg daily and injection of Ampicillin 25 mg/kg every 12 hours and Amikacin 7.5 mg/kg every 12 hours for one week plus oral drop vitamin A 3000 U (manufactured by

Hamadan School of Pharmacy) per neonate weight daily for 28 days

Category

Treatment - Drugs

2

Description

Control group: Just routine care including surfactant 5 ml/kg daily and injection of Ampicillin 25 mg/kg every 12 hours and Amikacin 7.5 mg/kg every 12 hours for one week

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr Maryam Mohamadai

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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mayamohamadi63@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Maryam Mohamadai

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Behnaz Basiri

Position

Podiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street addressSchool of Public Health, Hamadan University of
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Hamadan

Province

Hamadan

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

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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