

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of two maintenance doses of caffeine citrate 5 and 10 on premature retinopathy in very low birth weight infants

Protocol summary

Study aim

The effect of two maintenance doses of caffeine citrate 5 and 10 on premature retinopathy in very low birth weight infants

Design

A clinical trial with two parallel groups, three-blind, randomized with random number table on 100 patients.

Settings and conduct

This study is a three-blind clinical trial. In this study, 100 infants weighing less than 1500 grams in two equal groups, including 50 infants in each group, were included in the study, and caffeine citrate was prescribed for all these infants to prevent apnea caused by prematurity. Then the maintenance dose for each group including the first group receive caffeine at a dose of 5 mg / kg per day and the second group receive caffeine citrate at a dose of 10 mg / kg per day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All infants weighing less than 1500 grams Exclusion criteria: Major anomalies, Metabolic disease

Intervention groups

The first group receives caffeine at a dose of 5 mg / kg per day and the second group receives caffeine citrate at a dose of 10 mg / kg per day.

Main outcome variables

Retinopathy of prematurity in very low birth weight infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049985N1**

Registration date: **2021-02-10, 1399/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

Registration date

2021-02-10, 1399/11/22

Registrant information

Name

Shahram Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 6963

Email address

sh.moradi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of two maintenance doses of caffeine citrate 5 and 10 on premature retinopathy in very low birth weight infants

Public title

The effect of two maintenance doses of caffeine citrate 5 and 10 on premature retinopathy in very low birth weight infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All infant who weigh less than 1500 grams.

Exclusion criteria:

Major anomalies Metabolic diseases

Age

From **1 day** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning the subjects after applying the entry and exit criteria will be randomly assigned in a block method. The randomization unit is individual. The size of the blocks is 4 and in each block, each intervention group will be repeated twice.

Blinding (investigator's opinion)

Double blinded

Blinding description

The ophthalmologist who will play the role of ROP assessor in the studied infants, the physician in charge of the treatment (project manager) and the patient (infant) will be unaware of the study process and the separation of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2020-11-21, 1399/09/01

Ethics committee reference number

IR.MUBABOL.REC.1399.386

Health conditions studied

1

Description of health condition studied

Retinopathy

ICD-10 code

H35.1

ICD-10 code description

Retinopathy

Primary outcomes

1

Description

Retinopathy

Timepoint

According to gestational age between 4 to 6 weeks after birth.

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group receives caffeine citrate at a dose of 5 mg / kg per day.

Category

Treatment - Drugs

2

Description

Intervention group: The second group receives caffeine citrate at a dose of 10 mg / kg per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Shahram Moradi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
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Vice- Chancellor for Research Technology Affairs,
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Email
info@mubabol.ac.ir
Web page address
<http://research.mubabol.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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
Babol University of Medical Sciences
Full name of responsible person
Shahram Moradi
Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments