

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Anthropometric Outcome and Edema in Low Birth Weight Infants Treated With Erythropoietin

Protocol summary

Study aim

Determining the effect of erythropoietin treatment in low birth weight infants height, weight, headache, and neonatal edema

Design

A randomized clinical trial with a control group, parallel groups, phase 3, on 80 infants. Lottery is used for randomization.

Settings and conduct

Birth weight, height, and head circumference are measured. In the test group one week after the birth, RETIC and CBCdiff are checks and two weeks after birth Erythropoietin injection, three times a week for a month (12 times) dose of 100 units per kilogram of 2000 units ampules with subcutaneous injection of the baby's arm, two One week after the last Erythropoietin injection, the labels will be checked again and in the control group without injection. The experiments will be performed in the first two weeks and 40 days. After injection, the side-effects of Erythropoietin injection include an allergic reaction and problems with the injection. In both groups, the drug is held daily at the time of hospitalization. After discharge, the drug checks on time for injection, and the last time by the time of the trial.

Participants/Inclusion and exclusion criteria

Admission: age less than 35 weeks, birth weight less than 2000 g, no disease Withdrawal: anomaly, sepsis, thrombocytopenia, diastolic more than 60 mg, shock, hydrops, trisomies, seizures, hemolytic diseases

Intervention groups

Injecting erythropoietin in the intervention group for 12 sessions and checking its outcome in forty days and not intervening in the control group.

Main outcome variables

Improvement in the infant's recovery, infant's sucking and swallowing power, infant's general condition, prevention of neonatal apnea, improved neonatal anthropometric criteria, and decreased edema.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160511027853N2**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

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Farahnaz Mohammadkhaniha

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Anthropometric Outcome and Edema in Low Birth Weight Infants Treated With Erythropoietin

Public title

"Evaluation of the effect of Erythropoietin on Anthropometric results"; "Evaluation of the effect of Erythropoietin on Edema"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature birth with gestational age at birth less than 35 weeks Birth weight less than 2000 grams No illness (healthy babies who experience no problems or sickness in the first week of birth).

Exclusion criteria:

Congenital anomalies depression thrombocytopenia diastolic pressure greater than 60 mmHg shock hydrops fetalis threesomes seizures hemolytic diseases.

Age

From **7 days** old to **40 days** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80 neonates, 40 balls for the intervention group, and 40 balls for the control group are placed in a lottery container, and then the balls are randomly removed from the container without replacement and the created sequence is recorded.

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 Qazvin University of Medical Sciences

Street address

Kosar Hospital, Taleqani Ave, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.QUMS.REC.1398.133

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

prematurity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Around the head

Timepoint

Birth, one week after birth, two weeks after birth, forty days after birth

Method of measurement

Tape Measure

2**Description**

Weight

Timepoint

Birth, one week after birth, two weeks after birth, forty days after birth

Method of measurement

Baby digital scale with SCEA brand, Model 374, which weighs 5 grams

3**Description**

Edema

Timepoint

daily

Method of measurement

Pitting Edema Grading Scale

4**Description**

Height

Timepoint

Birth day and forty day of birth

Method of measurement

Tape Measure

Secondary outcomes

1

Description

The general condition of the neonate

Timepoint

every hour

Method of measurement

General examination of infants in terms of tachypnea, cyanosis, lactation, excretion, weight gain

Intervention groups

1

Description

Intervention group: Anthropometric characteristics of infants include birth weight, height, and head circumference. The RETIC and CBCdiff are tested one week after birth. Two weeks after birth, Erythropoietin is given three times a week for a month (12 times). The 2000 u Erythropoietin ampule produced by Sinagen Pharmaceutical Company is used, 100 units per kilogram for each baby. The tests are re-checked two weeks after the last Erythropoietin injection. In the control group, without drug injection, the tests are performed at 14 and 40 days of age. After the injection, the injection side-effects and edema are examined. Finally, the anthropometric tests and criteria are compared before and after the intervention. If Erythropoietin is effective, the primary consequences are increased in neonatal improvements, such as sucking and swallowing power, secondary outcomes, including; improved neonatal general condition, prevention of neonatal apnea, improved neonatal anthropometric criteria, and reduced edema.

Category

Treatment - Drugs

2

Description

Control group: These babies are prone to infection and malaise due to their pre-term. At the discretion of the Clinical Ethics Committee, no placebo is used for this group and they receive routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Educational and Medical Center

Full name of responsible person

Dr. Seyed Hooshyar Mojabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Farahnaz Mohammadkhaniha

Position

Educational Supervisor
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start accessing data immediately after the article is published

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other conditions

From where data/document is obtainable

Refer to Dr. Seyed Hoshyar Mojabi

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

Giving an email to Dr. Seyed Hoshyar Mojabi and answering within a week at most

Comments