

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of erythropoietin versus control group on the short-term prognosis in newborns with hypoxic- ischemic- encephalopathy: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of erythropoietin versus control group on the short-term prognosis in newborns with hypoxic- ischemic- encephalopathy

Design

This is a randomized clinical trial, phase II, in which 64 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible newborns with hypoxic- ischemic- encephalopathy 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 drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Newborn, Hypoxic- ischemic- encephalopathy Exclusion criteria: Congenital anomalies, Gestational age less than 36 weeks, Unperforated anus, Intracranial hemorrhage

Intervention groups

Intervention group: Routine treatment plus intravenous injection of erythropoietin 1000 U/kg/day on the first, second and third days and then every other day on the fifth, seventh, and ninth days to a maximum of 6 doses
Control group: Just routine treatment

Main outcome variables

Primary outcome: Seizure attacks, time of onset of consciousness, the occurrence of death, duration of hospitalization, time to start oral nutrition
Secondary outcome: Drug complications such as induced topical hypothermia, bradycardia, subcutaneous, and thrombocytopenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N334**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **prospective**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

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

2020-02-04, 1398/11/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of erythropoietin versus control group on the short-term prognosis in newborns with hypoxic-ischemic- encephalopathy: a randomized clinical trial

Public title

Effect of erythropoietin versus control group on the short-term prognosis in newborns with hypoxic-ischemic- encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newborn, Hypoxic- ischemic- encephalopathy

Exclusion criteria:

Congenital anomalies, Gestational age less than 36 weeks, Unperforated anus, Intracranial hemorrhage

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 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

2019-12-07, 1398/09/16

Ethics committee reference number

IR.UMSHA.REC.1398.759

Health conditions studied

1

Description of health condition studied

Hypoxic ischemic encephalopathy

ICD-10 code

P91.6

ICD-10 code description

Hypoxic ischemic encephalopathy [HIE]

Primary outcomes

1

Description

Seizure attacks

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

2

Description

Time of onset of consciousness

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

3

Description

Occurrence of death

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

4

Description

Duration of hospitalization

Timepoint

From the beginning of the intervention to two weeks thereafter

Method of measurement

Based on the medical document

5

Description

Time to start oral nutrition

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

By taking a history

Secondary outcomes

1

Description

Drug complications such as induced topical hypothermia, bradycardia and subcutaneous necrosis

Timepoint

From the beginning of the intervention until two weeks later

Method of measurement

With clinical examination

2

Description

Drug complications such as thrombocytopenia

Timepoint

From the beginning of the intervention up to two weeks later

Method of measurement

By laboratory tests

Intervention groups

1

Description

Intervention group: Routine treatment plus intravenous injection of erythropoietin 1000 U/kg/day on the first, second and third days and then every other day on the fifth, seventh, and ninth days to a maximum of 6 doses

Category

Treatment - Drugs

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr Tayebah Ghalandari Navideh

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3828 3939

Email

dr.ghalandari1@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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

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 Tayebah Ghalandari Navideh

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 911 432 1196

Email

dr.ghalandari1@gmail.com

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

b.basiri@umsha.ac.ir

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 address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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