# 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 Fatemieh 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

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Iran (Islamic Republic of)

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**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 Tayebeh Ghalandari Navideh
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Fatemieh Hospital, Pasdaran Ave.
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## Sponsors / Funding sources

**1**

**Sponsor**
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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 Tayebeh Ghalandari Navideh

**Position**
Resident of Pediatrics
**Latest degree**
Medical doctor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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