Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effects of erythropoietin and placebo on lesion size and outcome (Glasgow Outcome Score) in the severe brain-injured patients

Protocol summary

Summary

The purpose of this study is to investigate the effect of erythropoietin on size of brain lesions and outcome in patients with severe head injury. Severe brain-injured patients (Glasgow coma scale less than or equal to 8) with a single brain lesion volume less than 30 ml or those who have diffuse axonal injury are to be included and those who need surgical operation, polycythemic cases and those may not be followed during the project will be excluded from the study. Brain-injured cases with occurrence time more than 8 hours also are not to be included. In this double-blind study 60 patients will be randomly divided into two groups of 30. Patients in intervention group will be received erythropoietin 33000 IU in 50 ml normal saline during 30 min as an infusion. Erythropoietin will be repeated in the same dose 24 and 48 hours later. In another arm of the study, normal saline will be infused instead of erythropoietin as placebo. All of the patients will be checked for CT- Scan and laboratory tests including, hematocrite, hemoglobin, complete blood count, platelet count, ferritin and iron levels, electrolytes, glucose, blood urea nitrogen and creatinine before, 15 and 30 days after intervention and results will be recorded. Patients will be called 3 and 6 months after the beginning of the study, and their Glasgow outcome score will be recorded. Finally, analysis will be performed and patients' results will be compared regarding brain lesion size and outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072414138N1**
Registration date: **2013-09-08, 1392/06/17**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2013-09-08, 1392/06/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of erythropoietin and placebo on lesion size and outcome (Glasgow Outcome Score) in the severe brain-injured patients

Public title

Effect of erythropoietin on outcome of severe brain

injured patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: severe brain injury (Glasgow coma scale less than or equal to 8) with a single brain lesion volume less than 30 ml or those who have diffuse axonal injury; age between 15-65 years; no need for surgical operation; possibility of following up during the study period; having informed consent from first-degree relatives. Exclusion criteria: mild to moderate brain injury; patients with massive brain lesions(more than 30 ml volume); age less than 15 and over 65; surgical operation; cases with neoplasia in skull; multiple trauma; myeloproliferative diseases; polycythemia; sensitivity to erythropoietin; hyperkalemia; creatinine more than 3 mg/dl; all patients that their following- up is not guaranteed during the study; participating other trials; history of deep vein thrombosis; pregnancy; clinical brain death (without brain stem reflexes).

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotb-e ravandi Blvd.

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8719674591

Approval date

2013-05-18, 1392/02/28

Ethics committee reference number

29/5/1/625/پ

Health conditions studied

1

Description of health condition studied

Traumatic brain injury

ICD-10 code

S06.2 , S0

ICD-10 code description

Diffuse brain injury , Focal brain injury

Primary outcomes

1

Description

Patient's outcome

Timepoint

3 and 6 month after intervention

Method of measurement

Based on Glasgow coma scale

2

Description

Lesion size

Timepoint

Before, 15 and 30 days after intervention

Method of measurement

Based on CT-Scan and radiologist's report

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: After the arrival of the patient into the study and within 8 hours after the occurrence of the brain Injury, erythropoietin will be infused at the rate of 33000 IU/50 ml normal saline /30 min intravenously. This dosage will be repeated in next 24 and 48 hours.

Category

Treatment - Drugs

2

Description

In the control group: After the arrival of the patient into the study and within 8 hours after the occurrence of the brain Injury, normal saline will be infused at the rate 50 ml in 30 minutes intravenously. This dosage will be repeated in next 24 and 48 hours.

Category

Treatment - Drugs

Recruitment centers

1

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Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
Kashan University of Medical Sciences, Deputy of Research
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
Kashan University of Medical Sciences, Deputy of Research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty