Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessment of the effect of Albumin compared with Placebo on the reduction of the hematoma volume in patients with Hemorrhagic Stroke referred to Ahvaz Golestan Hospital

Protocol summary

Summary

(1) Objectives : Assessment of the effect of Albumin on the reduction of the hematoma volume in patients with Hemorrhagic Stroke. (2) Design : Randomized, Double-blind, Placebo-controlled, Single central, Phase 2 trial. (3) Setting and conduct : Patients with Hemorrhac Stroke in the last 24 hours of onset are randomly allocated in two groups; The case group is received Albumin form vials of human Albumin 20% and the control group is recived saline 0.9% as Placebo. The hematoma volume is calculated on CT scan befor and at the end of intervention (After one week). The results is compared between groups. In addition, the neurological deficits are estimated by NIHSS criteria befor intervention and one month later then results is compared between groups. (4) Participants including major eligibility criteria : 60 patients. Major inclusion criteria : Primary Hemorrhagic Stroke; 24 hours from symptom onset; above 18 years old. Major exclusion criteria : Need surgical evacuation; Allergy to Albumin; Severe cardiac or renal failure. (5) Intervention : 1- Vials of human Albumin 20% 1 g/kg divided in 7 days within daily IV infusion during 2 hours in case group; 2- Saline 0.9% (with an equal volume of 1 gr/kg from human Albumin 20% vial) in 7 days within 2 hours IV infusion as Placebo in control group. (6) main outcome measures (variables) : 1- The hematoma volume; 2- The neurological deficits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201018574N1**
Registration date: **2013-02-13, 1391/11/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

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Davood Shalilahmadi
Name of organization / entity
Ahvaz Jundishapur University Of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Albumin compared with Placebo on the reduction of the hematoma volume in patients with Hemorrhagic Stroke referred to Ahvaz Golestan Hospital

Public title

Effect of Albumin on size of hematoma in Hemorrhagic Stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria : Primary Hemorrhagic Stroke; 24 hours from symptom onset; Above 18 years old. Exclusion Criteria : Hematoma volume less than 7 ml; Need surgical evacuation; Pregnancy; Lactation; Systolic blood pressure less than 100 mmHg or more than 250 mmHg; Anticoagulant or Thrombolytic therapy; Serum Creatinine more than 2 mg/dl; History of known allergy to Albumin; History of severe allergic reactions known as latex gloves; Exacerbation of congestive heart failure within the past 6 months; Acute myocardial infarction in the last 6 months.

Age
From **18 years** old to **149 years** old

Gender
Both

Phase
2

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
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Esfand St, Golestan Blv.

City
Ahvaz

Postal code
61357-15794

Approval date
2011-08-26, 1390/06/04

Ethics committee reference number
ETH-203

Health conditions studied

1

Description of health condition studied
Hemorrhagic Stroke

ICD-10 code
I61.9

ICD-10 code description
Intracerebral Haemorrhage, Unspecified

Primary outcomes

1

Description
The hematoma volume

Timepoint
Befor intervention, The end of intervention (One week)

Method of measurement
The hematoma volume on CT scan (ml) : Length of maximum appearance of hematoma (cm) × Width of same cut (cm) × Number of cuts including bleeding / 2

Secondary outcomes

1

Description
Neurological deficits

Timepoint
Befor intervention, After one month

Method of measurement
NIHSS criteria

Intervention groups

1

Description
Vials of human Albumin 20% : 1 gram per kiloogram body weight divided in 7 days within daily IV infusion during 2 hours

Category
Treatment - Drugs

2

Description
Saline 0.9% (with an equal volume of 1 gr/kg from human Albumin 20% vial) in 7 days within 2 hours IV infusion

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Davood Shalilahmadi, MD

Street address

Nosrat St, Golestan Blv.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mostafa Feghhi, MD

Street address

Esfand St, Golestan Blv.

City

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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

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

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

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Resident of Neurology

Other areas of specialty/work

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Other areas of specialty/work

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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