

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of intravenous albumin in mortality and morbidity of intracranial hemorrhage; a randomized clinical trial

Protocol summary

Summary

The aim of this study was to evaluate the effect of Albumin on hemorrhagic stroke. Through a double blind randomized clinical trial, 60 stroke patients were randomly allocated in two groups. The control group received placebo while the intervention group received Albumin (1 g/kg/7days within 2 hours at any time; dosage form: 50 cc vial of human albumin 20%). Functional outcome were recorded according to NIHSS scales before treatment and at end of the first week and the end of the third month . The results compared between groups.

General information

Acronym

ACHIEVE

IRCT registration information

IRCT registration number: **IRCT201111288240N1**

Registration date: **2012-06-05, 1391/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

Name

Morteza Oghbaei

Name of organization / entity

JondiShapur Ahvaz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3012

Email address

oghbaei.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-09-06, 1390/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous albumin in mortality and morbidity of intracranial hemorrhage; a randomized clinical trial

Public title

Effect of Albumin in Hemorrhagic Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1.Primary supratentorial ICH; 2.< 24 hours from symptom onset; 3.Age >18. Exclusion Criteria: 1.ICH volume < 7 cc; 2.Glasgow Coma Scale < 8; 3.Surgical evacuation anticipated; 4.Pregnancy; 5. Breastfeeding; 6.Hemodynamic instability (SBP < 100 mmHg, > 200 mmHg); 7.Current participation in another experimental treatment protocol; 8.Renal impairment with GFR < 30 or Creatinine > 2.0; 9.History of or known allergy to albumin; 10. History of or known severe allergy to rubber latex; 11.Episode/exacerbation of congestive heart failure (CHF) from any cause in the last 6 months. (An episode of congestive heart failure is any heart failure that required a change in medication, diet or hospitalization); 12.Acute myocardial infarction in the last 6 months; 13.Elevated serum troponin level on

admission > 0.1 mcg/L; 14. Known valvular heart disease with CHF in the last 6 months; 15. Known (or in the investigator's judgment) existence of severe aortic stenosis or mitral stenosis; 16. Cardiac surgery involving thoracotomy (e.g., coronary artery bypass graft (CABG), valve replacement surgery) in the last 6 months; 17. Suspicion of aortic dissection on admission; 18. Acute arrhythmia (including any tachy- or bradycardia) with hemodynamic instability on admission (systolic blood pressure < 100 mmHg); 19. Findings on physical examination of any of the following: (1) jugular venous distention (JVP > 4 cm above the sternal angle), (2) 3rd heart sound, (3) resting tachycardia (heart rate > 100/min) attributable to congestive heart failure, (4) abnormal hepatojugular reflux, (5) lower extremity pitting edema attributable to congestive heart failure or without apparent cause, (6) bilateral rales, and/or (7) if a chest x-ray is performed, definite evidence of pulmonary edema, bilateral pleural effusion, or pulmonary vascular redistribution; 20. Current acute or chronic lung disease requiring supplemental chronic or intermittent oxygen therapy; 21. Prosthetic heart valves; 22. Documented left ventricular ejection fraction < 35%.

Age

From **18 years** old to **83 years** old

Gender

Both

Phase

3

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**

JondiShapour Ahvaz University of Medical Sciences

Street address

JondiShapour Ahvaz University of Medical Sciences,
Golestan

City

Ahvaz

Postal code**Approval date**

2011-03-04, 1389/12/13

Ethics committee reference number

408/3

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

hemoragic Stroke

ICD-10 code

I61.2

ICD-10 code description

Intracerebral haemorrhage in hemisphere, unspecified

Primary outcomes**1****Description**

Patient Functional Outcome

Timepoint

At admission time, after one week and after 3 months

Method of measurement

NIHSS

Secondary outcomes**1****Description**

Morbidity and Mortality

Timepoint

At the admision, after one week and 3 month

Method of measurement

Registration of mortality

2**Description**

Drug side effects

Timepoint

At the admision, after one week and 3 months

Method of measurement

Drug side effects chart

Intervention groups**1****Description**

20% Vial Human Albumin with total dosage of 1 gram per kilogram Body Weight infusion during 7 days within 2 hours daily

Category

Treatment - Drugs

2**Description**

Placebo Vial as the Same Dose of Albumin
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Morteza Oghbaei, MD

Street address

Neurology Department, Golestan Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

JondiShapur Ahvaz university of Medical Sciences

Full name of responsible person

Mehdi Norouzi, MD

Street address

JondiShapur Ahvaz university of Medical Sciences,
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City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

JondiShapur Ahvaz 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

JondiShapurAhvaz University of Medical Sciences

Full name of responsible person

Morteza Oghbaei, MD

Position

Resident of Neurology

Other areas of specialty/work**Street address**

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

JondiShapurAhvaz University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mohammadianinejad, MD

Position

Asistant of professor

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Person responsible for updating data

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Name of organization / entity

JondiShapur Ahvaz University of Medical Sciences

Full name of responsible person

Morteza Oghbaei, MD

Position

Neurology Resident

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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