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 NIHS 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
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Iran (Islamic Republic of)
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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/د

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

Plasebo 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, Golestan

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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

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

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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