Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of nitroglycerin infusion and labetalol in acute arterial hypertension controlling in intracerebral hemorrhage patients admitted to intensive care unit

Protocol summary

Study aim
Comparison of Nitroglycerin and Labetalol infusion in controlling arterial hypertension in patients with intracerebral hemorrhage in the intensive care unit

Design
The current study was conducted as interventional study with control group.

Settings and conduct
In this interventional study, 20 patients with intracerebral hemorrhage admmited to intensive care unit of Urmia Imam Khomeini Hospital were treated with Labetalol (intervention group) and 34 patients with Nitroglycerin serum (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with intracerebral hemorrhage; Arterial hypertension; Patients admitted to the intensive care unit. Exclusion criteria: Patients with a history of cerebral neoplasm; having a history of cerebrovascular diseases; having a history of cardiovascular disease

Intervention groups
Intervention group: 20 mg of Labetalol (as bolus form) in primary dose as intravenously and each 20 minutes was given as a bolus dose of 20-80 mg. Control group (routine treatment): Nitroglycerin was prescribed as continuous infusion with 5 µg primary dose per minute and up to 200 µg per minute to control blood pressure.

Main outcome variables
Systolic and diastolic blood pressures

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171221037983N2**
Registration date: **2018-05-02, 1397/02/12**
Registration timing: **retrospective**

Last update: **2018-05-02, 1397/02/12**
Update count: **0**

Registration date
2018-05-02, 1397/02/12

Registrant information
Name
Mohammad Amin Valizadeh
Name of organization / entity
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Iran (Islamic Republic of)
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valizademohammadamin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2017-09-21, 1396/06/30

Actual recruitment start date
2017-03-21, 1396/01/01

Actual recruitment end date
2017-09-21, 1396/06/30

Trial completion date
empty

Scientific title
Comparison of nitroglycerin infusion and labetalol in acute arterial hypertension controlling in intracerebral hemorrhage patients admitted to intensive care unit

Public title
The effect of Nitroglycerin and Labetalol on hypertension

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with intracerebral hemorrhage Patients with arterial hypertension Patients admitted to the intensive care unit
Exclusion criteria:
Patients with history of brain neoplasm History of cerebrovascular diseases History of cardiovascular diseases
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Actual sample size reached: **54**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients were unaware of which of the study groups were.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Ershad street; Modarres Blvd; Imam Khomeini Teaching Hospital; Urmia; Iran
City
Urmia
Province
West Azarbaijan
Postal code
5711453590
Approval date
2016-12-20, 1395/09/30
Ethics committee reference number
umsu.rec.1395.110

Health conditions studied

1

Description of health condition studied
Intracerebral hemorrhage
ICD-10 code
I61
ICD-10 code description
Nontraumatic intracerebral hemorrhage

Primary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Every hour in the first 24 hours after intervention
Method of measurement
SAADAT ALBURZ B9 Monitoring device

Secondary outcomes

1

Description
Severity of disease
Timepoint
Before and after intervention
Method of measurement
GCS score

Intervention groups

1

Description
Intervention group: 20 mg of Labetalol (as bolus form) in primary dose as intravenously and each 20 minutes was given as a bolus dose of 20-80 mg.
Category
Treatment - Drugs

2

Description
Control group: Nitroglycerin was prescribed as continuous infusion with 5 µg primary dose per minute and up to 200 µg per minute to control blood pressure.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Urmia Imam Khomeini Teaching Hospital

Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei

Street address
Ershad Street; Modarres Blvd; Imam Khomeini Hospital; Urmia; Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Iraj Mohebbi

Street address
Jahad street; Resalat Blvd; Urmia University of Medical Sciences; Urmia; Iran

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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei

Position
Anesthesiologist

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Publication of the results on paper
When the data will become available and for how long
end of 2018 year
To whom data/document is available
free access
Under which criteria data/document could be used
as article
From where data/document is obtainable
by searching in databases
What processes are involved for a request to access data/document
without limitations
Comments