

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 admitted 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

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9935

Email address

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

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
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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
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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