Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of intravenous propofol infusion with conservative treatment in outcome of patients with severe intracerebral hemorrhage hospital based

Protocol summary

Study aim

Comparison of the efficasy of 24-hour intravenous propofol infusion with conservative treatment in outcome of patients with severe intracerebral hemorrhage

Design

After selecting the patients and explaining the study and the purposes of the study for their legal status, written consent was obtained and patients randomly assigned to the study will be divided into two groups receiving propofol infusion and control group patients.

Settings and conduct

After obtaining permission from the Ethics Committee of Qom University of Medical Sciences, the present study will be conducted in a clinical trial in patients with intracerebral hemorrhage who are not candidates for craniotomy. The implementation of this research project will be undertaken with the informed consent of the study and the medicines and their effects on all patients or their relatives, and it will be possible to withdraw from the study at any time without difficulty. The study site of the teaching hospitals in Qom city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients with acute ICH aged 15 years or older • Having a NIHSS score above 15 • No surgical indication by the neurosurgical team Exclusion criteria: • A history of allergy to the drugs used in the study • Pregnancy and lactation • Chronic renal failure, liver or any concomitant chronic illness • Concomitant malignancy

Intervention groups

The present study will be a clinical trial on patients with severe intracerebral hemorrhage (NIHSS> 15) who are not candidates for craniotomy. The experimental group will receive propofol intravenous infusion at a dose of 75-75 µg / kg / min for the first 24 hours in addition to the usual care and treatment used in the control group.

Main outcome variables

Mean mRS; NIHSS; mortality rate; length of hospitalization; intubation time; extent of bleeding; rate of edema and bleeding complications

General information

Reason for update

Acronym

ICH(intracerebral hemorrhage)

IRCT registration information

IRCT registration number: **IRCT20200208046414N1**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **prospective**

Last update: **2020-04-04, 1399/01/16**
Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

Farideh Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4633 3297

Email address

dr.farideh.z92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intravenous propofol infusion with conservative treatment in outcome of patients with severe intracerebral hemorrhage hospital based

Public title

"Effect of propofol in severe intracerebral hemorrhage "

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute ICH over 15 years of ages No surgery indication by the neurosurgery team NIHSS above 15

Exclusion criteria:

Pregnancy &lactation Concurrent Malignancy CKD or chronic hepatic failure or another chronic sickness History of drug sensitivity used in the study

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

At all stages of the study, the researchers responsible for evaluating the outcome of the patients would be blind to the grouping performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

No.83, 4th Ave., Jahad Daneshgahi Ave., Safa Shahr Blvd.

City

Qom

Province

Ghoum

Postal code

37169-93456

Approval date

2020-03-12, 1398/12/22

Ethics committee reference number

IR.MUQ.REC.1398.156

Health conditions studied

1

Description of health condition studied

Nontraumatic intracranial hemorrhage

ICD-10 code

I62.9

ICD-10 code description

Nontraumatic intracranial hemorrhage, unspecified

Primary outcomes

1

Description

NIHSS

Timepoint

onset of study . 7th day .90th day

Method of measurement

table of NIHSS

2

Description

MRS

Timepoint

Onset of study . 7th and 90th day

Method of measurement

Table of MRS

3

Description

Brain Edema

Timepoint

3th & 7th day

Method of measurement

Brain CT scan

4

Description

Expansion of Hemorage

Timepoint

3th &7th day

Method of measurement

Brain CT scan

Secondary outcomes

1

Description
Time of Hospitalization
Timepoint
End of hospitalization
Method of measurement
day

2

Description
Mortality rate
Timepoint
mortality
Method of measurement
yes /no

3

Description
Time of intubation
Timepoint
End of Intubation
Method of measurement
day

4

Description
Complication
Timepoint
End of study
Method of measurement
Brain CT

Intervention groups

1

Description
In addition to routine treatment and care, a 25-75 µg / kg / min intravenous infusion will be used within the first 24 hours. NIHSS, GCS and bleeding volume will be recorded on arrival and daily for up to 7 days. Also, mortality rate, duration of hospitalization, extent of hemorrhage and mRS, NIHSS, GCS in the group receiving propofol will be compared using appropriate statistical tests. Cardiac wall, measurement of oxygen saturation of peripheral blood by pulse oxy meters, standard neurological treatments and standard rehabilitation measures will be performed.
Category
Treatment - Drugs

2

Description
Control group: In patients of the intervention group routine supportive measures in patients with intracerebral hemorrhage hospitalized in the intensive care unit such as blood pressure measurement, ECG monitoring, measurement of peripheral blood oxygen saturation by pulse oximeter, standard neurological treatments and Standard rehabilitation procedures will be performed. All demographic and clinical information of patients will be recorded in questionnaires designed by researchers and the amount of mRS, NIHSS, GCS and bleeding volume will be recorded at the beginning of the day and up to 7 days. Also, mortality rate, duration of hospitalization, extent of hemorrhage expansion and rate of mRS, NIHSS, GCS in the control group will be compared using appropriate statistical tests. Standard neurological treatments and standard rehabilitation measures will be performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital complex
Full name of responsible person
Ehsan sharifipour
Street address
Shahid Beheshti St.
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3612 2000
Email
f.zamani1371@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr Ehsan Sharifipour
Street address
Faculty of Medicine. Pardis Complex. in front of Yadegar Imam Stadium.Ghadir Boulevard
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sharifipour.e@muq.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Dr Ehsan Sharifipour
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for updating data

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Resident
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dr.farideh.z92@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available