Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Importance of timing in craniotomy in Spontaneous intracereberal haemorrhage

Protocol summary

Study aim
To determine the importance of timing in craniotomy in spontaneous intracerebral haemorrhage

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site. Sample size of the study was 70.

Settings and conduct
The study was conducted at Khyber Teaching Hospital. The outcome assessor in study was blinded. The group has been regularly followed up with imaging to see whether the treatment has worked or not.

Participants/Inclusion and exclusion criteria
For this study, the inclusion criteria were patients ranging from 18 to 70 who were diagnosed with spontaneous ICH and confirmed by neuroimaging to have a Glasgow Coma Scale (GCS) score of 5–18. Patients who have traumatic intracerebral bleeding, all the cases requiring surgical intervention, and every deep-seated bleeding, coagulopathy, pregnancy, or pre-existing neurological condition that could affect results were excluded from this study.

Intervention groups
A randomly assigned intervention group (medical management) was treated through regular medical care in line with set guidelines, without cutoff monitoring of vital signs and neurological status, as well as timely intervention for complications. The group has been regularly followed up with imaging to see whether the treatment has worked or not.

Main outcome variables
Functional independence measure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230907059376N4**
Registration date: **2024-02-14, 1402/11/25**
Registration timing: **retrospective**

Last update: **2024-02-14, 1402/11/25**
Update count: **0**

Registration date
2024-02-14, 1402/11/25

Registrant information

Name
Sarmad Khattak

Name of organization / entity
Rehman Medical Institute, Peshawar

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-09-16, 1401/06/25

Actual recruitment start date
2022-02-03, 1400/11/14

Actual recruitment end date
2022-08-17, 1401/05/26

Trial completion date
2022-09-03, 1401/06/12

Scientific title
Importance of timing in craniotomy in Spontaneous intracereberal haemorrhage

Public title
Importance of timing in craniotomy in Spontaneous intracereberal haemorrhage: experience in tertiary care hospital
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients age range from 18 to 70 years Patients of both genders, i.e. male and female Patients who were diagnosed with spontaneous ICH and confirmed by neuroimaging to have a Glasgow Coma Scale (GCS) score of 5-18
Exclusion criteria:
Patients who have traumatic intracerebral bleeding All the cases requiring surgical intervention Deep-seated bleeding, coagulopathy, pregnancy, or pre-existing neurological conditions that could affect results were excluded from this study.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we implemented randomization to ensure unbiased allocation of participants to treatment groups. We employed block randomization, grouping participants based on specific criteria, and then randomly assigning them to treatment groups within each block. This method helps maintain balance across treatment groups and controls for potential confounding variables. Randomization was carried out at the individual level, ensuring each participant had an equal chance of being assigned to any treatment group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome assessors were blinded to treatment assignments through the utilization of sealed envelopes containing group allocations, ensuring impartial evaluation of study outcomes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committe of khyber teaching hospital
Street address
University Rd, Rahat Abad, Peshawar, Khyber Pakhtunkhwa, Pakistan
City
Peshawar
Postal code
25000
Approval date
2022-01-12, 1400/10/22
Ethics committee reference number
kth/ns/2022/02

Health conditions studied

1

Description of health condition studied
Intracranial Haemorrhage
ICD-10 code
I62.9
ICD-10 code description
Nontraumatic intracranial hemorrhage, unspecified

Primary outcomes

1

Description
Functional Independance measure
Timepoint
The measurement was taken at baseline and after 90 days
Method of measurement
A modified Ranken scale was used to assess the functional independance measure

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This approach involved providing standard medical care without immediate surgical intervention. Specifically, patients received routine medical attention aimed at stabilizing their condition and managing symptoms. This included pharmacological interventions such as medications to control blood pressure, pain management, and other supportive measures. However, crucially, these patients did not undergo surgical procedures such as craniotomy for hematoma evacuation.Additionally, patients in the medical

management group did not undergo continuous monitoring of vital signs and neurological status, nor was there a predefined cutoff point for initiating surgical intervention based on changes in these parameters. Instead, they were managed conservatively with medical therapy alone, with interventions for complications initiated as clinically indicated rather than preemptively.

Category

Treatment - Drugs

2

Description

Intervention group: Patients assigned to the early surgical intervention group received a more aggressive treatment approach involving prompt surgical intervention within 24 hours of symptom onset. This involved performing a craniotomy procedure aimed at evacuating the hematoma and achieving control of the bleeding source. The surgical intervention was conducted promptly to minimize the potential deleterious effects of the hematoma, such as increased intracranial pressure and compression of vital brain structures.Unlike the medical management group, patients in the early surgical intervention group underwent surgical procedures aimed at directly addressing the underlying pathology causing their symptoms. This proactive approach aimed to expedite hematoma evacuation and prevent further neurological deterioration associated with delayed surgical intervention.Following the surgical procedure, patients in both groups were regularly monitored and followed up with imaging studies to assess the efficacy of the treatment approach. This allowed clinicians to evaluate the resolution of the hematoma, assess for any complications related to the intervention, and track the overall clinical progress of the patients over time.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Khyber Teaching Hospital, Peshawar
Full name of responsible person
Muhammad Idrees Khan
Street address
University Rd, Rahat Abad, Peshawar, Khyber Pakhtunkhwa, Pakistan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Khyber Teaching Hospital, Peshawar

Proportion provided by this source

25

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
Afridi Medical Complex, Peshawar
Full name of responsible person
Mahboob Khan
Position
Consultant Neurosurgeon
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be provided under the title importance of timing in craniotomy in Spontaneous intracereberal haemorrhage: experience in a Tertiary care hospital

When the data will become available and for how long

Data will be available after approval of RCT

To whom data/document is available

Data will be available to neurosurgeons and medical students

Under which criteria data/document could be used

Data will be used after approvla from principle author

From where data/document is obtainable

Data will be obtained through email to principle author Muhammad Idris Khan idrisnsw83@gmail.com

What processes are involved for a request to access data/document

Process is simple. Just the seeker have to email the author

Comments