

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Importance of timing in craniotomy in Spontaneous intracerebral 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 intracerebral haemorrhage

Public title

Importance of timing in craniotomy in Spontaneous intracerebral 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 committee 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 Independence measure

Timepoint

The measurement was taken at baseline and after 90 days

Method of measurement

A modified Rankin scale was used to assess the functional independence 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

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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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Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa

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Name of organization / entity

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Full name of responsible person

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Latest degree

Specialist

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)

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 intracerebral
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 approval from principle author

From where data/document is obtainable

Data will be obtained through email to principle author
Muhammad Idris Khan idrisnw83@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