

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Pakistan

##### Phone

+92 91 5838666

##### Email address

sarmadkhattak007@gmail.com

#### 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 Ranken 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

##### Street address

University Rd, Rahat Abad, Peshawar, Khyber Pakhtunkhwa, Pakistan

##### City

Peshawar

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25000

##### Phone

+92 91 9224400

##### Email

idrisnsw83@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khyber Teaching Hospital, Peshawar

##### Full name of responsible person

Muhammad Idrees Khan

##### Street address

University Rd, Rahat Abad, Peshawar, Khyber Pakhtunkhwa, Pakistan

##### City

Peshawar

##### Postal code

25000

##### Phone

+92 91 5711751

##### Email

idrisnsw83@gmail.com

#### 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

##### Street address

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

##### City

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##### Province

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mehboob509@gmail.com

## Person responsible for scientific 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

**Contact**

**Name of organization / entity**

Afridi Medical Complex, Peshawar

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Khyber Pakhtunkhwa

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25150

**Phone**

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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 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 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**