Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Study the effect of computed tomography without contrast in management of patients after moderate traumatic brain injury in a randomized clinical trial

Protocol summary

Study aim
Determining the effect of computed tomography without contrast in management of patients after moderate traumatic brain injury

Design
Randomized Clinical Trial open-label

Settings and conduct
Patients referred to the emergency department of Vali-e-Asr Hospital in Fasa who meet the inclusion criteria are identified by the neurosurgeon and the objectives of the study are explained to the patient or companion and take their written consent. Patients are divided into intervention and control arms. Patients in both arms will be transferred to a neurosurgery ICU. For all patients at zero, a CT scan of the brain will be taken without contrast. Questionnaires are then completed by trained ICU nurses and neurosurgeons.

Participants/Inclusion and exclusion criteria
In this study, patients in the age range of 19 to 95 years who have been admitted to the emergency room of Hazrat Vali Asr Fasa Hospital due to brain trauma, will be included in the study with all the following conditions: The patient is in the first 6 hours after the onset of symptoms The patient was taken CT scan without contrast Glasgow Coma Score scale The patient should be between 8 and 14 The patient is not a candidate for neurosurgical surgery The patient's vital signs are completely stable without inotropic drugs The patient is not pregnant The patient has no seizures or no focal neurological deficit

Intervention groups
A follow-up CT routine will be performed for all patients 6 hours after the initial CT scan in the control arm. In the intervention arm, patients will have a follow-up CT scan at 6 hours after the initial CT based on the occurrence of each of the following four: Any change in GCS Change in pupil size by more than one millimeter Change in the reaction of one or two pupils to light The emergence of any new focal neurological deficit

Main outcome variables
Need for surgical interventions; Death

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210509051232N1**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date
2021-08-06, 1400/05/15

Registrant information

Name
Adrina Habibzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 71 3835 5957

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adrina.hbz77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of computed tomography without contrast in management of patients after moderate traumatic brain injury in a randomized clinical trial

Public title

the effect of computed tomography without contrast in management of patients after moderate traumatic brain injury

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is in the first 6 hours after the onset of symptoms According to the PECARN criteria, the patient was taken without a brain contrast agent at the time of CT scan Glasgow Coma Score scale of the patient should be between 8 and 14 The patient is not a candidate for neurosurgical surgery The patient or his first-degree companion is willing to participate in the study consciously The patient is not a candidate for emergency surgery from another service The patient's vital signs are completely stable without the need for inotropic drugs The patient is not pregnant The patient does not have Anisocoria The patient has no seizures or no focal neurological deficit

Exclusion criteria:

Glasgow Coma Score scale=3 and bilaterally fixed dilated pupils From the beginning of the study, the patient may experience a drop in GCS The need for neurosurgery or any other surgery at any time from the start of the study The unwillingness of the patient or his first-degree companions to participate in the study Lack of trust in the patient's neurological examination for any reason (psychologic cases, low compliance of the patient or companions, initiation of sedative drugs) Perform a brain CT scan for any reason earlier than 6 hours after the initial CT scan Previous use of anticoagulant drug

Age

From **19 years** old to **95 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

After generating a random sequence using random allocation software. Patients with eligibility conditions were selected by convenience sampling and randomly divided into groups with and without follow-up CT scans by randomized 4-way permutation blocks. It should be noted that the list prepared with tags will be kept secret for hiding. Patients are divided into intervention and control arms.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ebne Sina Square, Fasa

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2021-08-03, 1400/05/12

Ethics committee reference number

IR.FUMS.REC.1400.045

Health conditions studied

1

Description of health condition studied

moderate traumatic brain injury

ICD-10 code

S06.9

ICD-10 code description

Unspecified intracranial injury

Primary outcomes

1

Description

Need for surgical intervention

Timepoint

6 hours and 30 day

Method of measurement

Patient file

Secondary outcomes

1

Description
Death
Timepoint
6 hours and 30 days
Method of measurement
patient file

2

Description
length of hospital stay
Timepoint
6 hours and 30 days
Method of measurement
patient file

Intervention groups

1

Description
Control group: Head CT scan without contrast routinely in all patients, In the control arm, a follow-up routine CT will be performed for all patients 6 hours after the initial CT scan. Also, all patients are admitted to the intensive care unit of neurosurgery and neurological examinations are performed every half an hour. Neurological examination includes Glasgow Coma Scale (GCS), pupil size, pupil light response, focal neurological deficit, vital signs, cerebral nerve examination 3, 4, 6, 10, and manual muscle test (MMT).
Category
Diagnosis

2

Description
Intervention group: Head CT scan without contrast, if the doctor decides, based on the patient's clinical condition, In the intervention arm, patients will have a follow-up CT scan at 6 hours after the initial CT based on the occurrence of each of the following four cases: 1. Any change in the Glasgow Coma Scale (GCS) 2. Change of more than one millimeter in pupil size (one or two-sided) 3. Change in the reaction of one or two pupils to light 4. The appearance of any new focal neurological deficit. Also, all patients are admitted to the intensive care unit of neurosurgery and neurological examinations are performed every half an hour. Neurological examination includes Glasgow Coma Scale (GCS), pupil size, pupil light response, focal neurological deficit, vital signs, cerebral nerve examination 3, 4, 6, 10, and manual muscle test (MMT).
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-asr hospital
Full name of responsible person
Reza Taheri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Adrina Habibzadeh

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
All data can be published after being unidentifiable

When the data will become available and for how long
Information will be available without a time limit

To whom data/document is available
Qualified persons according to the publisher's rules

Under which criteria data/document could be used
For scientific use with detailed mention of the source

From where data/document is obtainable
Refer to Publisher / Contact via the author's email address

What processes are involved for a request to access data/document
Information can be provided after correspondence via academic email

Comments