

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

investigate efficacy of fibrinogen blood level correction between 1.5 - 2 gr/lit to above 2 gr/lit with bleeding rate during operation and post operation hospital course in traumatic brain injury

Protocol summary

Study aim

the evaluation of relation between correction of fibrinogen level (1.5-2.0 grm/lit) in traumatic brain injury to > 2.0 grm/lit and peri operational bleeding

Design

randomizaing with coin flipping (head or tail), parallel group trial with blinded outcome and data collection, sample volume will be chosen by explained duration (between March 2019 to March 2020) according to numbers and data of samples we will collected

Settings and conduct

patients who underwent craniotomy whom fibrinogen level is between 1.5 to 2.0 gr/lit are include and we exclude patients who have coagulopathy in lab data like abnormal PT,PTT,INR, platelets counts or coagulopathy disorders history or underwent another major surgery. patients are devided to patients whose fibrinogen level are corrected to > 2.0 gr/lit and the rest by randomizaing with coin flipping (head or tail), None of patients, sergeuns and who collect data know about grouping of paitents. in this study we compare bleeding valume in peri operative priods and increasing ratio of bleeding of peri operative brain CT scan in non operative sites.

Participants/Inclusion and exclusion criteria

patients who are brought to Emtiaz hospital ER, affiliated to Shiraz Univercity of medical sciemces, Shiraz, Iran, between March 2019 to March 2020 and underwent craniotomy whom fibrinogen level is between 1.5 to 2.0 gr/lit are include in our study patients who have coagulopathy in lab data such as abnormal PTwe exclude the patients who have coagulopathy in lab data such as abnormal PT,PTT,INR, platelets counts or history of coagulopathy disorders or underwent another major surgery from other services in this admission before skull craniotomy surgery from our study

Intervention groups

correction of serum fibrinogen level (1.5-2.0 grm/lit) to >

2.0 grm/lit

Main outcome variables

peri operative bleeding valume rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190129042541N1**

Registration date: **2019-02-13, 1397/11/24**

Registration timing: **prospective**

Last update: **2019-02-13, 1397/11/24**

Update count: **0**

Registration date

2019-02-13, 1397/11/24

Registrant information

Name

amin niakan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3625 4206

Email address

aniakan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigate efficacy of fibrinogen blood level correction between 1.5 - 2 gr/lit to above 2 gr/lit with bleeding rate during operation and post operation hospital course in traumatic brain injury

Public title

investigate efficacy of fibrinogen blood level correction and bleeding volume in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients who are older than sixteen years and brought to Emtiaz hospital ER, affiliated to Shiraz University of medical sciences, Shiraz, Iran, between March 2019 to March 2020 and underwent skull craniotomy whom fibrinogen level is between 1.5 to 2.0 gr/lit are include in our study

Exclusion criteria:

patients who have coagulopathy in lab data such as abnormal PTwe exclude the patients who have coagulopathy in lab data such as abnormal PT,PTT,INR, platelets counts or history of coagulopathy disorders or underwent another major surgery from other services in this admission before skull craniotomy surgery from our study

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

randomizaing with coin flipping (head or tail), if flipped coin shows head (picture side of coin), we put patient in fibrinogen corrected group and if flipped coin shows tail (amount of money coin side coin), we put patient in fibrinogen in uncorrected group

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 Shiraz University of Medical Sciences

Street address

Emtiaz Hospital, shahid chamran Blvd

City

Shiraz

Province

Fars

Postal code

7194815711

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.SUMS.MED.REC.1397.340

Health conditions studied**1****Description of health condition studied**

intra cranial bleeding in traumatic brain injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes**1****Description**

blood volume rate

Timepoint

pre operatio and post operation

Method of measurement

blood volume messurment during operation and in hemovac and post operatin, blood volume messurment in pre and post operation CT scan

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: pre operation or during surgery intra venous fibrinogen injection was down patient. , if serum fibrinogen level is between 175 to 200 mg per lit, one gram fibrinogen was injected ,and if serum fibrinogen level is between 150 to 200mg per lit, two gram fibrinogen was injected

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emtiaz hospital

Full name of responsible person

Amin Niakan

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Emtiaz hospital, Chamran Blvd, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor of research . shiraz university of medical sciences

Full name of responsible person

younes ghasemi

Street address

7th floor, Central building of Shiraz University of Medical Sciences

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71345-1978

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Email

vcrdep@sums.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

vice chancellor of research . shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Amin Niakan

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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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

No - There is not 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

all data except personal patients data

When the data will become available and for how long

6 months after data publication

To whom data/document is available

all researcher

Under which criteria data/document could be used

no extra condition

From where data/document is obtainable

researcher should refer to emtiaz hospital

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

Written request from amin niakan

Comments