Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 colected

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 valume 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 Univercity of medical sciemces,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

Street address
Emtiaz hospital, Chamran Blvd, Shiraz, Iran

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Shiraz

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7194815711

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+98 71 3625 4206

Email
aniakan@sums.ac.ir

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

City
Shiraz

Province
Fars

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71345-1978

Phone
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Fax
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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

Contact

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences
Full name of responsible person
Amin Niakan
Position
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Other areas of specialty/work
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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