

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of prothrombin Concentrate complex on reverse of bleeding due to Rivaroxaban in critically ill patients admitted to intensive care unit

Protocol summary

Study aim

Effect of prothrombin Concentrate complex on reverse of bleeding due to Rivaroxaban in critically ill patients admitted to intensive care unit

Design

Clinical trial with intervention and control groups, with parallel groups, Double-blind, randomized trial

Settings and conduct

All patients in Neurology, General Imam Reza and orthopedic shohada Hospital

Participants/Inclusion and exclusion criteria

criteria for entering the study includes rivaroxaban use and ages over of 18 years. Exclusion criteria include: Sensitivity of octaplex, patient dissatisfaction ,History of receiving antiplatelet drugs, NSAIDs, oagulation disorders associated with chronic liver disease, IgA deficiency, Ambulatory history,Thrombotic disorders

Intervention groups

Control group: Patients with bleeding in the use of rivaroxaban Which have been treated with FFP. Study Group: Patients with bleeding in the use of rivaroxaban Which have been treated withPCC

Main outcome variables

blood loss volume and the number of units transfused and blood products

General information

Reason for update

Acronym

PCC

IRCT registration information

IRCT registration number: **IRCT20091012002582N20**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

Registration date

2018-08-19, 1397/05/28

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prothrombin Concentrate complex on reverse of bleeding due to Rivaroxaban in critically ill patients admitted to intensive care unit

Public title

Effect of prothrombin Concentrate complex on reverse of bleeding due to Rivaroxaban

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who admitted in ICU with major bleeding and Life threatening related to Rivaroxaban
Exclusion criteria:
Unwillingness of the patient Allergic to PCC History of receiving antiplatelet drugs&NSAIDs

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

no case

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Building No. 2, Tabriz University of Medical Sciences, Golghast St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-04-13, 1397/01/24

Ethics committee reference number

IR.TBZMED.REC.1397.124

Health conditions studied

1

Description of health condition studied

Abnormal finding of blood chemistry, major bleeding

ICD-10 code

R79.9 Abno

ICD-10 code description

Abnormal finding of blood chemistry, major bleeding due to coagulopathy

Primary outcomes

1

Description

he amount of bleeding in rivaroxaban use

Timepoint

duration of ICU stay

Method of measurement

blood loss volume and hemodynamic changes

Secondary outcomes

1

Description

the number of units transfused and blood products

Timepoint

From the bleeding time to the stop bleeding

Method of measurement

Measure the number of units transfused and blood products

Intervention groups

1

Description

The intervention group will treat bleeding with P.C.C at 45-50 IU / Kg

Category

Treatment - Other

2

Description

Control group:hemorrhage treatment will consist of 15-10 cc FFP per kilogram of body weight along with crystalloid resuscitation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

General ICU, Imam Reza hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

Imam Reza hospital, Golgasht street

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2

Recruitment center

Name of recruitment center

Shohada hospital ICU

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

Position

Director of ICU, Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

Paria sedagh

Position

Resident of Anesthesiology

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Medical doctor

Other areas of specialty/work

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available