Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Evaluation of Tranexamic acid effect on upper gastrointestinal bleeding outcomes

Protocol summary

Summary

This double-blind randomized clinical trial study designed to evaluate tranexamic acid efficacy on upper gastrointestinal bleeding management. Eligible patients (age more than 18 years old and accept to contribute in the study, as well as no contraindication for tranexamic acid) after initial resuscitation will divide to two groups: 1.intervention group: further standard treatment of gastrointestinal treatment, these patients will receive 1 gr intravenous tranexamic acid in 10 minutes , as well as another same dose in next 8 hours; 2.control group: further standard treatment of gastrointestinal treatment, these patients will receive placebo. Initial evaluation of patients will perform by upper gastrointestinal endoscopy, and then patients will check for needs for emergent endoscopy or surgery, rebleeding, need for blood transfusion and death related to gastrointestinal bleeding. Finally all data will analyze for evaluation of tranexamic acid effect on upper gastrointestinal bleeding outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112911956N4**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Morteza Talebi Doluee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dr. Mohsen Tafaghodi, Educational Assistance, Mashhad University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Tranexamic acid effect on upper gastrointestinal bleeding outcomes

Public title

Tranexamic acid efficacy in reduction of upper gastointestinal bleeding complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with signs and symptoms of upper gastrointestinal bleeding, which will present to emergency ward and have all of these conditions: age more than 18 years old and hemodynamically stable condition(systolic blood pressure more than 90 mmHg and pulse rate less than 110 bpm), as well as accept to contribute in the study(by consent form). Exclusion criteria: age less than 18 years old; pregnancy and

breast feeding; Tranexamic Acid contraindications: history of thromboembolic disorders, nephrotic syndrome, current estrogen consumption, history of allergy to tranexamic acid or variceal hemorrhage; patients that need to anticoagulant therapy; probable DIC; history of epilepsy or brain disorders; cancer (except for who has been treated and no recurrence has occurred in one years ago).

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Mashhad, Shahid Fakoori blvd, Health and Knowledge town, Zakaria building, First floor, Postal code: 345

City
Mashhad

Postal code
9177899191

Approval date
2014-07-26, 1393/05/04

Ethics committee reference number
930035

Health conditions studied

1

Description of health condition studied
Upper gastrointestinal haemorrhage

ICD-10 code
K92.0

ICD-10 code description
Haematemesis

Primary outcomes

1

Description
Decrease in mortality of upper gastrointestinal bleeding

Timepoint
one week

Method of measurement
Questionnaire

Secondary outcomes

1

Description
decrease in rebleeding

Timepoint
24 houres

Method of measurement
Questionnaire

2

Description
decrease in need to endoscopic treatment

Timepoint
24 houres

Method of measurement
Questionnaire

3

Description
decrease in need to blood component transfusion

Timepoint
first week

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: after standard treatment of upper GI bleeding, these patients would receive intravenously 1 gr tranexamic acid (100 and 250 mg vials are available) in 10 minutes, then 1 gr tranexamic acid will prescribe slow intravenously in next 8 houres.

Category
Treatment - Drugs

2

Description
Control group: after standard treatment of upper GI bleeding, these patients would receive normal saline as placebo, as same the intervention group, first in a vial in

10 minutes and then slow intravenously in next 8 houres.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Educational, Research and Treatment Center

Full name of responsible person

Sanaz Javdani Masroor Tanha

Street address

Emam Reza Square, Ebne Sina Avenue, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreyshi Building, Daneshgah Strees, Mashhad

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty