

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessment of effect of topical Tranexamic Acid on management of acute upper gastrointestinal bleeding in patients presented to emergency department

Protocol summary

Summary

Tranexamic Acid is used in a wide range of haemorrhagic conditions. The drug may reduce all-cause mortality in gastrointestinal bleeding but there are some reports about complications of systemic TA administration. However, topical TA was found effective in controlling bleeding in patients with hemorrhagic diathesis and to our knowledge there is no report of its topical use in UGIB. The goal of the current study was to determine the efficacy of a single dose of TA, administered topically, on bleeding from the benign peptic lesions. All patients with symptoms or signs of GI bleeding who will refer to Hazrat Rasool Emergency Department will be assessed. This is a double blind randomized controlled clinical trial study. Participants will undergo endoscopy within 24 hours of admission and each patient with UGIB due to benign peptic lesions will be enrolled. We compare the amount of Packed RBCs, rebleeding episodes, 30-day mortality and probable complication (thrombosis) between intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201148721N1**

Registration date: **2012-11-06, 1391/08/16**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2012-11-06, 1391/08/16

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 1103

Email address

rezaei-m@razi.tums.ac.ir

Recruitment status

Not enough for processing

Funding source

Private Resources (Attending physician and resident)

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of topical Tranexamic Acid on management of acute upper gastrointestinal bleeding in patients presented to emergency department

Public title

Effect of topical Tranexamic Acid on management of gastrointestinal bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Symptoms or signs of GI bleeding.

Exclusion Criteria: Pregnancy; Lactation; Gastrointestinal Malignancy; Coagulopathy; History of Thromboembolism; History of myocardial infarction or ischemic

cerebrovascular accident; End Stage Renal Disease; Allergy to TA; Undergoing anticoagulation therapy; Congenital or acquired coagulopathy; who were reluctant to enroll in this study.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

Tehran University of Medical Sciences

Street address

Jalalieh St., Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-05-07, 1391/02/18

Ethics committee reference number

90 / 2781 / 130 / ۵

Health conditions studied

1

Description of health condition studied

Upper Gastrointestinal Bleeding

ICD-10 code

K29.0

ICD-10 code description

Acute haemorrhagic gastritis

Primary outcomes

1

Description

Packed RBC

Timepoint

from intervention to discharge

Method of measurement

patient hospital document

Secondary outcomes

1

Description

30-day Mortality

Timepoint

From intervention to 1 month later

Method of measurement

Patients' Hospital Document and Phone Contact

2

Description

Tranexamic Acid Complication

Timepoint

during the study

Method of measurement

According to clinical manifestation, physical examination and doppler sonography

3

Description

Re-bleeding

Timepoint

From intervention to Discharge

Method of measurement

Patients' Hospital Document

Intervention groups

1

Description

Intervention group: In addition to conventional therapy, we add 1 gram tranexamic acid, diluted into 500cc normal saline, to gastric washing fluid. we used Tranexamic Acid Ampule manufactured by Caspian company in Rasht, Iran.

Category

Treatment - Drugs

2

Description

Control group: In addition to conventional therapy, we add free water (similar to tranexamic acid ampule) to fluid water for gastric washing.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital

Full name of responsible person

Mahdi Rezai

Street address

Hazrat Rasool hospital, Niayesh St., Sattarkhan St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private Resiurces (Attending and Resident of incharge)

Full name of responsible person

Mahdi Rezai

Street address

Emergency Department of Hazrat Rasool Hospital, Niayesh St., Sattarkhan St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Private Resiurces (Attending and Resident of incharge)

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

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Rezai

Position

Emergency Medicine Resident

Other areas of specialty/work

Street address

Hazrat Rasool hospital, Tehran

City

Tehran

Postal code

Phone

+98 21 8868 1103

Fax

Email

rezaei-m@razi.tums.ac.ir ; mah_re@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Rezai

Position

Emergency Medicine Resident

Other areas of specialty/work

Street address

Hazrat Rasool hospital, Tehran

City

Tehran

Postal code

Phone

+98 21 8868 1103

Fax

Email

rezaei-m@razi.tums.ac.irmah_re@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Rezai

Position

Emergency Medicine Resident

Other areas of specialty/work

Street address

Hazrat Rasool Hospital

City

Tehran

Postal code

Phone

+98 21 8868 1103

Fax

Email

rezaei-m@razi.tums.ac.irmah_re@yahoo.com

Web page address

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