

# 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 / 5

## 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**

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**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

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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*