Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

TOPICAL TRANEXAMIC ACID AS A NOVELTREATMENT FOR BLEEDING GASTRIC ULCER

Protocol summary

Summary

The aim of study was to evaluate the efficacy of topical tranexamic acid for the treatment of gastrointestinal hemorrhage due to bleeding peptic ulcers. Patients who were known to be less than 18 years of age with the diagnosis of bleeding gastric or duodenal ulcer were studied provided there were no contraindication for endoscopy. One hundred twenty patients were evaluated for gastrointestinal bleeding. A total of 21 patients(10girls,11boys) aged 1 month to 15 years were recruited in the study. In an interventional study, patients were randomly divided into two groups. In case group tranexamic acid was administered directly on the bleeding ulcer during endoscopy . In control group epinephrine (1/10000) was applied on the ulcer as the standard endoscopic therapy. Both drugs were administered during endoscopy after the patients were hospitalized for the control of GI bleeding. The rate of re-bleeding, the number of blood transfusions and the duration of hospital stay were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306105330N6**
Registration date: **2014-02-24, 1392/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-24, 1392/12/05

Registrant information

Name

Mandana Rafeey

Name of organization / entity

Liver and gastrointestinal research center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1331 4135

Email address

rafieem@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-08-30, 1391/06/09

Expected recruitment end date

2013-08-30, 1392/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

TOPICAL TRANEXAMIC ACID AS A NOVELTREATMENT FOR BLEEDING GASTRIC ULCER

Public title

TOPICAL TRANEXAMIC ACID FOR GASTRIC ULCER

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Endoscopic diagnose of bleeding duodenal or gastric ulcer; patient age less than 18 years. Exclusion Criteria: Contraindication for endoscopy; another disease or co-morbidity; coagulopathy; altered post-surgical anatomy of the stomach or duodenum; presence of portosystemic shunt; treatment by other endoscopic or surgical modalities within 14 days prior to

the intended application of tranexamicacid(TXA); patients with hemodynamic instability and a drop in hemoglobin(Hb) level more than 2 g/dl in two hours.

Age
To **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **21**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City
Tabriz

Postal code

Approval date
2014-01-27, 1392/11/07

Ethics committee reference number
92181

Health conditions studied

1

Description of health condition studied
peptic ulcer

ICD-10 code
k25

ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
the evidence of clinically recurrent bleeding

Timepoint
within first two days after index endoscopy

Method of measurement
confirmed clinically or by diagnostic upper gastrointestinal endoscopy or surgery

Secondary outcomes

1

Description
the number of blood transfusions and hospital stay duration

Timepoint
during hospitalization

Method of measurement
by clinician

Intervention groups

1

Description
In case group, 4-5 milliliter of tranexamic acid(500mg/5ml vial) was administered directly on the bleeding ulcer .This treatment was used as a single dose during endoscopy .

Category
Treatment - Drugs

2

Description
In control group, 4-5 milliliter of epinephrine (1/10000) was administered directly on the bleeding ulcer .This treatment was used as a single dose during endoscopy.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children Hospital

Full name of responsible person

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Ali Meshkini
Street address
Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
Tabriz
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
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
Tabriz university of medical sciences
Full name of responsible person
Dr Maryam Shoaran
Position
Assistant Professor
Other areas of specialty/work
Street address
Tabriz children hospital, Sheshgelan St, Tabriz, Iran
City
Tabriz
Postal code
Phone
+98 41155262250
Fax
Email
mrafeey@yahoo.com, rafieem@tbzmed.ac.ir, maryamshoaran1@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mandana Rafeey
Position
Professor
Other areas of specialty/work
Street address
Tabriz children hospital, Sheshgelan St, Tabriz, Iran
City
Tabriz
Postal code
Phone
+98 41 1526 2250
Fax
Email
mrafeey@yahoo.com, rafieem@tbzmed.ac.ir, maryamshoaran1@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mandana Rafeey
Position
Professor
Other areas of specialty/work
Street address
Tabriz children hospital, Sheshgelan St, Tabriz, Iran
City
Tabriz
Postal code
Phone
+98 41 1526 2250
Fax
Email
mrafeey@yahoo.com, rafieem@tbzmed.ac.ir, maryamshoaran1@gmail.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