

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

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Name of organization / entity

Liver and gastrointestinal research center, Tabriz
University of Medical Sciences

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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 tranexamic acid (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

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Professor

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Position

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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*