

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of transaxic acid effect on treatment of admitted patients due to upper gastrointestinal bleeding

Protocol summary

Study aim

Investigation of Tranexamic-Acid effect on treatment of admitted patients due to upper gastrointestinal bleeding

Design

This study is one-blinded clinical trial. The study population included all patients admitted to the Kermanshah hospital with diagnosis of upper gastrointestinal bleeding. Approximately 70 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study, which will be carried out at Imam Reza hospital in Kermanshah city, is one-blinded, that patients will be blinded to the study groups, the dosage of the drug and the manufacturer of the medicine. At the beginning of the study, the rate and severity of bleeding will be recorded in a checklist

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diagnosed upper gastrointestinal bleeding exclusion criteria: Patients with renal failure and subarachnoid hemorrhage; Sensitivity to drug; Bleeding of urinary tract

Intervention groups

The first intervention group will receive the usual treatment of upper gastrointestinal bleeding (fluid therapy and pentoprazole infusion). The second intervention group will be treated with intravascular injections with a dose of one gram of infusion intravenous stat, and then with one gram Tranexamic-Acid every 8 hours, in addition to the usual treatment (liquid therapy and infusion of pentoprazole).

Main outcome variables

The upper gastrointestinal tract amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N92**

Registration date: **2018-06-06, 1397/03/16**

Registration timing: **prospective**

Last update: **2018-06-06, 1397/03/16**

Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2638-03-23, 2017/01/03

Expected recruitment end date

2639-03-11, 2017/12/20

Actual recruitment start date

2638-05-22, 2017/03/01

Actual recruitment end date

2638-05-22, 2017/03/01

Trial completion date

empty

Scientific title

Investigation of transaxic acid effect on treatment of admitted patients due to upper gastrointestinal bleeding

Public title

The effect of transaxic acid on upper gastrointestinal bleeding

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diagnosed upper gastrointestinal bleeding

Exclusion criteria:

Patients with renal failure and subarachnoid hemorrhage

Sensitivity to drug Bleeding of urinary tract

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Individually randomization method using a random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients were blinded to the dosage of the drug and the manufacturer of the drug in comparison to the study groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

ir.kums.rec.1397.004

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**

The upper gastrointestinal tract amount of bleeding

Timepoint

During the study

Method of measurement

Using information recorded in the patients file

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group will receive the usual treatment of upper gastrointestinal bleeding (fluid therapy and pentoprazole infusion).

Category

Treatment - Drugs

2**Description**

The second intervention group, in addition to the usual treatment (fluid therapy and pentoprazole infusion), will be treated with Tranxamic Acid Monosaccharide (Caspian) Company (Rasht, Iran) with 1 g infusion intravenous stat and then one gram each 8 hours with Transxamic Acid.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Parastar Boulevard

Full name of responsible person

Mehdi Hamzeei
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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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

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person

Mehdi Hamzeei
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Resident of Internal
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments