Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effectiveness of oral Tranexamic Acid in control of gastrointestinal bleeding in patients with acute upper gastrointestinal bleeding

Protocol summary

Study aim
Effectiveness of Oral Tranexamic Acid on Prevention and Complications of Acute Upper Gastrointestinal Bleeding

Design
A triple-blind randomized controlled clinical trial with a parallel group design of 375 patients, enrolled between January 2019 and September 2020.

Settings and conduct
This study will be done in the gastroenterology ward, Imam Khomeini Hospital. To decreasing of bias; patients, evaluator, and the analyzer will be unaware of treatment and case groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with Acute Upper Gastrointestinal Bleeding Exclusion Criteria: Patients with Clean base and Malignant Ulcer

Intervention groups
Patients with acute upper gastrointestinal bleeding will be divided into 3 groups: 2 intervention group and 1 control group. One of the intervention group will be treated with 1000 milligrams Tranexamic Acid for 3 days, another intervention group will be given 500 milligrams of drug and 500 milligrams of placebo for 3 days. Control group will be given 1000 milligrams of placebo for 3 days. Placebo has the same appearance, size, taste, and color with the drug.

Main outcome variables
Gastrointestinal Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190116042380N1**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **registered_while_recruiting**
Last update: **2019-03-04, 1397/12/13**
Update count: **0**

Registration date
2019-03-04, 1397/12/13

Registrant information

Name
Naghme Habibi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3292 1839

Email address
habibi.n@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-06, 1397/10/16

Expected recruitment end date
2019-09-07, 1398/06/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of oral Tranexamic Acid in control of gastrointestinal bleeding in patients with acute upper gastrointestinal bleeding

Public title
The effectiveness of oral Tranexamic Acid on prevention of rebleeding in patients with acute upper gastrointestinal bleeding

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients With Acute Upper Gastrointestinal Bleeding
Exclusion criteria:
Patient's discontent Clean base Ulcers in Endoscopy Malignant Ulcers in Endoscopy
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **375**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced allocation to groups A to C in successive blocks: we will divide each letters A, B, C to a special treatment conventional. Then start from block 1, means; First patient will receive C treatment, Second patient will receive A treatment and... The first six patients were all over, we will start block 2 for the seventh patient, and in the same way to finish. BLOCK 1 1: C 2: A 3: A 4: B 5: B 6: C BLOCK 2 1: B 2: A 3: C 4: B 5: A 6: C
Blinding (investigator's opinion)
Triple blinded
Blinding description
Drug and Placebo have been Prescribed for Patients in separated packets.Physician, Nurse, Patient and Data Analyser Are Unaware About Packets, But the Patients's Name and Packet Code Are Noted First of All.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jundi Shapoor Medical Sciences Ethics Committee
Street address
Azadegan Street
City
Ahvaz
Province
Khouzestan
Postal code
61357-12794
Approval date
2019-01-05, 1397/10/15
Ethics committee reference number
IR.AJUMS.REC.1397.741

Health conditions studied

1

Description of health condition studied
Acute Upper Gastrointestinal Bleeding
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Gastrointestinal Bleeding
Timepoint
one, Two and Three Days After Drug Consumption
Method of measurement
Hemoglubin Drop, Gastrointestinal Rebleeding

Secondary outcomes

1

Description
Hemoglobin Drop
Timepoint
Gastrointestinal Rebleeding
Method of measurement
Serial Hemoglobin measurement

Intervention groups

1

Description
Control group: participants in this group was given four 250 mg placebo capsule (Corn Starch) daily, for 3 days.
Category
Placebo

2

Description
Intervention group 1: participants in this group was given four 250 mg tranexamic acid (Amin Pharma co.) capsule daily, for 3 days.
Category
Treatment - Drugs

3

Description

Intervention group 2: participants in this group was given two 250 mg tranexamic acid (Amin Pharma co.) capsule and two placebo capsule (Corn Starch) daily, for 3 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Ahvaz

Full name of responsible person
Ali Akbar Shayeste

Street address
Azadegan Street

City
Ahvaz

Province
Khouzestan

Postal code
61357-12794

Phone
+98 61 3292 1839

Fax
+98 61 3292 1839

Email
dr_abazar_parsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Ali Akbar Shayeste

Street address
Azadegan Street

City
Ahvaz

Province
Khouzestan

Postal code
61357-12794

Phone
+98 61 3292 1839

Fax
+98 61 3292 1839

Email
dr_abazar_parsi@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Ali Akbar Shayesteh

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Azadegan Street

City
Ahvaz

Province
Khouzestan

Postal code
61357-12794

Phone
+98 61 3292 1839

Fax
+98 61 3292 1839

Email
habibi.n@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Ali Akbar Shayesteh

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Azadegan Street

City
Ahvaz

Province
Khouzestan

Postal code
61357-12794

Phone
+98 61 3292 1839

Fax
+98 61 3292 1839
Email
habibi.n@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Akbar Shayeste
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Azadegan Street
City
Ahvaz
Province
Khouzestan
Postal code
61357-12794
Phone
+98 61 3292 1839
Fax
+98 61 3292 1839
Email
habibi.n@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
information related to the main outcomes will be published.
When the data will become available and for how long
6 months after ending the study
To whom data/document is available
Researchers in Academic Institutes
Under which criteria data/document could be used
For Academic research
From where data/document is obtainable
Person responsible for scientific inquiries
What processes are involved for a request to access data/document
By sending Email, at least 2 months
Comments