

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of the effect of tranexamic acid and vasopressin on the outcome of severe gastrointestinal bleeding in patients referred to the emergency department

#### Protocol summary

##### Study aim

Comparison of the effect of vasopressin and tranexamic acid in controlling severe gastrointestinal bleeding and improving the outcome of patients referred to the emergency department

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 in 120 patients. Random blocking method was used for randomization.

##### Settings and conduct

This study is a randomized clinical trial study that is performed as a double blind on patients with a diagnosis of severe gastrointestinal bleeding, referred to the emergency room of Amir Al-Momenin and Valiasr hospitals in Arak. clinicians and data analyzers are blind. 120 patients are studied who are randomly divided into four groups. For all 4 groups, the patient is examined at the beginning of admission and the amount of bleeding and then the initial tests including: CBC DIFF, BUN, CR, NA, K, BS, PT, PTT, INR, are checked. Vital signs and blood transfusion rate are performed every half hour and tests are performed every 6 hours for 24 hours (4 times) CBC, BUN, CR re-check. To check the amount of bleeding, a graduated container or non-sterile gas is provided to the patient. The clinical condition of patients in all 4 groups is evaluated and recorded within 24 hours

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with a diagnosis of severe upper and lower gastrointestinal bleeding referred to the emergency department. exclusion criteria: vasopressin and tranexamic acid sensitivity, coagulation disorders, suspected acute myocardial infarction

##### Intervention groups

The first group: receiving intravenous tranexamic acid + common standard treatment Group 2: receiving intravenous vasopressin + common standard treatment Group 3: common standard treatment Group 4: receiving

both drugs + common standard treatment

##### Main outcome variables

Bleeding volume, blood pressure, heart rate, hemoglobin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190717044255N2**

Registration date: **2020-11-13, 1399/08/23**

Registration timing: **prospective**

Last update: **2020-11-13, 1399/08/23**

Update count: **0**

##### Registration date

2020-11-13, 1399/08/23

##### Registrant information

##### Name

Ali Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3276 7500

##### Email address

a.azizi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of tranexamic acid and vasopressin on the outcome of severe gastrointestinal bleeding in patients referred to the emergency department

**Public title**

Comparison of the effect of vasopressin and tranexamic acid on gastrointestinal bleeding

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with a diagnosis of severe upper or lower gastrointestinal bleeding

**Exclusion criteria:**

Previous allergy to vasopressin or tranexamic acid  
coagulation disorders Suspected acute myocardial infarction

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A total of 120 patients will be divided into four groups of 30 through random blocking with a size of 4 blocks. In this way, by online software (sealedenvelope.com) 30 random sequences of 4 of the names of the studied groups are generated and according to the obtained sequences, the patients will be assigned to different groups, respectively. Assigning individuals to groups using random blocking method will lead to allocation Concealment. In this way, first a random sequence is created by one of the mentioned methods, then based on the sample size of the research, a number of envelopes with aluminum wrappers (in order not to clarify the contents of the envelopes) are prepared and each of the random sequences is created. It is registered on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the

letter is opened in order and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is double-blind. In this study, patients will not be aware of the type of drug used and for this purpose, placebo will be used in the control group and only the main executor of the project is aware of the study groups and their drugs. The clinical caregiver and data analyzer are also unaware of the study groups and recognize them only by the letters A, B, C, and D.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Approval date**

2020-02-02, 1398/11/13

**Ethics committee reference number**

IR.ARAKMU.REC.1398.304

**Health conditions studied****1****Description of health condition studied**

Gastrointestinal bleeding

**ICD-10 code**

K92.2

**ICD-10 code description**

Gastrointestinal hemorrhage, unspecified

**Primary outcomes****1****Description**

Gastrointestinal bleeding volume

**Timepoint**

During the first 24 hours after receiving the drug

### **Method of measurement**

Using a Calibrated container or non-sterile gas (each blood gas completely impregnate with equivalent to 20 ml blood )

## **Secondary outcomes**

### **1**

#### **Description**

Blood pressure

#### **Timepoint**

Every 30 minutes to 24 hours after receiving the drug

#### **Method of measurement**

Automatic arm pressure gauge cuff

### **2**

#### **Description**

Pulse rate

#### **Timepoint**

Every 30 minutes to 24 hours after receiving the drug

#### **Method of measurement**

Pulse oximeter device

### **3**

#### **Description**

Patients venous hemoglobin concentration

#### **Timepoint**

When patients are admitted to the emergency room and then every 6 hours, up to 24 hours after receiving the drug

#### **Method of measurement**

Based on laboratory results by Cell counter device model H1

## **Intervention groups**

### **1**

#### **Description**

Control group: 30 patients will be treated with standard gastrointestinal bleeding treatment and the first placebo of normal saline will be infused 100 cc in 20 minutes and then 100 cc per hour for up to 4 hours. The second normal saline placebo will be injected at 100 cc per hour for up to 6 hours. Treatment with both types of placebo will be performed for patients from the time of admission.

#### **Category**

Placebo

### **2**

#### **Description**

Intervention group: Intervention group 1: 30 patients will be treated with standard gastrointestinal bleeding treatment and tranexamic acid drug from the beginning of hospitalization (Caspian drug, Iran) will first be infused at a dose of 10 mg / kg in the initial dose for 20 minutes and then 1mg / kg per hour as a maintenance dose for

up to 4 hours for the patient. Normal saline placebo is also injected simultaneously and 100 cc per hour for 6 hours for the patient.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention group 2: 30 patients will be treated with standard gastrointestinal bleeding treatment and vasopressin will be prescribed at the rate of 30 units per hour (at a rate of 0.5 units per minute) for 6 hours from the beginning of hospitalization (drug elixir, Iran). Normal saline placebo is also injected simultaneously and 100 cc infusion in the first 20 minutes and 100 cc per hour for 4 hours for the patient.

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Intervention group 3: 30 patients will be treated with standard gastrointestinal bleeding treatment and tranxamic acid drug from the beginning of hospitalization (Caspian drug, Iran) will first be infused at a dose of 10 mg / kg in the initial dose for 20 minutes and then 1mg / kg per hour as a maintenance dose for up to 4 hours is prescribed to the patient. Also, vasopressin is prescribed at the rate of 30 units per hour (at a rate of 0.5 units per minute) for 6 hours from the beginning of hospitalization (Elixir of Medicine, Iran).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Valiasr hospital

##### **Full name of responsible person**

Simin Najafgholian

##### **Street address**

Valiasr Sq.

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3814957558

##### **Phone**

+98 86 3223 1283

##### **Email**

pr\_valieasr@arakmu.ac.ir

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Amiralmomenin hospital

**Full name of responsible person**

Simin Najafgholian

**Street address**

Sardasht, basij sq.

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Email**

it-amiralmomenin@arakmu.ac.ir

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

۳۸۱۹۶۹۳۳۴۰

**Phone**

00980863136055

**Email**

info@arakmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Phone**

+98 86 3417 3639

**Email**

research@arakmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Simin najafgholian

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Simin Najafgholian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

5819396548

**Phone**

0098863136055

**Email**

info@arakmu.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Simin Najafgholian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3819693348

**Phone**

+98 86 3313 6055

**Email**

research@arakmu.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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