Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 in120 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

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Iran (Islamic Republic of)

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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
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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
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2

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Sponsors / Funding sources

1

Sponsor
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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
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

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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