Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Tranexamic acid on mortality and morbidity in spontaneously ICH patients

Protocol summary

Study aim
The effect of tranexamic acid on mortality and morbidity in spontaneous ICH patients

Design
This study is a double blind randomized clinical trial in Amir al-Momenin Hospital in Arak, Iran in 1398 with easy sampling method. This study is a double blind randomized clinical trial. All spontaneous ICH patients who meet the inclusion criteria will be assessed after completing the informed consent form as the study population. The responsible person is aware of the type of study and the study groups, while patients are not aware of the type of injectable drug.

Settings and conduct
This study was a double blind randomized clinical trial in Amir al-Momenin hospital in Arak. In this study 94 patients were randomly divided into two equal groups of placebo and tranexamic drug using block randomization method. Acids are divided

Participants/Inclusion and exclusion criteria
Arrival: Spontaneous ICH patients refer to emergency department of Arak Amir al-Momenin Hospital Exclusion: 1. The patient is a candidate for surgery. 2. The patient has a history of documented cerebral venous thrombosis (CVT) and venous thrombosis.

Intervention groups
In the intervention group, 47 patients with ICH spontaneously receive 1 gram bolus in the first 10 minutes and receive 1 gram intravenous infusion in the first 8 hours. In the control group, 47 patients with spontaneous ICH receive normal saline, 1 g bolus in the first 10 minutes and 1 g intravenous infusion in the first 8 hours.

Main outcome variables
If there is a significant relationship between the administration of tranexamic acid in spontaneous ICH patients and the non-proliferation of intracerebral hematoma in these patients, further studies can confirm this important effect on the prognosis of these patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191014045103N1**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **prospective**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date
2019-11-23, 1398/09/02

Registrant information

Name
Omid Ezati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3422 6135

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-06, 1398/09/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Tranexamic acid on mortality and morbidity in spontaneously ICH patients

Public title
Effect of Tranexamic acid on mortality and morbidity in spontaneously ICH patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Spontaneous ICH Patients Refer to Emergency Department of Arak Amiralmomenin Hospital in Arak
Exclusion criteria:
The patient is a candidate for surgery Patient with documented cerebral venous thrombosis (CVT) and documented venous thrombosis
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a randomized double-blind clinical trial study on 94 patients undergoing tranexamic acid injections who will divided into two equal groups using placebo and tranexamic acid by blocking randomization method.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study only the expert in charge of the study is aware of the type of study and study groups while patients are not aware of the type of injectable drug. Also, the intern in charge of the plan, which is responsible for filling in the checklist, is not aware of the type of injectable drug group and only knows the groups based on A and B and fills out the checklists accordingly.
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
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2019-08-04, 1398/05/13
Ethics committee reference number
IR.ARAKMU.REC.1398.138

Health conditions studied

1

Description of health condition studied
Intracerebral hemorrhage
ICD-10 code
I61.0
ICD-10 code description
Nontraumatic intracerebral hemorrhage in hemisphere, subcortical

Primary outcomes

1

Description
Duration of hospitalization
Timepoint
After the injection
Method of measurement
Admitted by checklist as number of days hospitalization

2

Description
Evaluation of the patient's clinical condition
Timepoint
After the injection
Method of measurement
Checklist and NIHSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 47 patients with spontaneous ICH receive tranexamic acid, 1 g bolus in the first 10 minutes and 1 g intravenous infusion in the first 8 hours. Patients are then assessed on the basis of a checklist including the number of days of hospitalization and clinical status based on the NHISS form.

Category
Treatment - Drugs

2

Description
Control group: 47 patients with spontaneous ICH receive normal saline as 1 gram bolus in the first 10 minutes and 1 gram intravenous infusion in the first 8 hours. Hospitalization and clinical status are assessed on the basis of the NHISS form.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Saeed Soltani

Street address
Sardasht

City
Arak

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Markazi

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3848176941

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+98 86 3417 3645

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjmandzadegan

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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

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Omid Ezati

Position
Medical intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Omid Ezati
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Other areas of specialty/work
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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