

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Email address

i.am.khodam.dg@gmail.com

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 be 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

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Rsearch@arakmu.ac.ir

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

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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

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

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Full name of responsible person

Omid Ezati

Position

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Latest degree

A Level or less

Other areas of specialty/work

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