

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Impact of administration of nebulized Tranexamic Acid in control of symptoms and outcome of patients with moderate and severe hemoptysis

Protocol summary

Study aim

Evaluation of the effect of inhaled Tranexamic acid in controlling symptoms and clinical improvement and outcome of patients with moderate and severe hemoptysis

Design

Clinical trials with control group, double blind, randomized blocks in 80 patients (two groups of 40)

Settings and conduct

All patients with moderate and severe hemoptysis over 15 years of age who are admitted to Emergency department of Imam Khomeini Hospital are included. Computerized randomization method gives each patient a special code (which is related to medicine or placebo). The appearance of the drug and placebo is completely identical and the patient and physician will be unaware of the substance content that is prescribed. The medication or placebo is nebulized in 4 doses at intervals of 12 hours for the patient, and then the information about the volume and frequency of hemoptysis and the need for invasive interventions and the duration of hospitalization are recorded and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients over 15 years old with moderate to severe hemoptysis referring to the emergency department. Exclusion criteria: history of allergy, active thromboembolic disease, lack of consent to participate in the study

Intervention groups

After obtaining patients' consent to enter the study, parallel to the usual treatments for control of symptoms in patients in the case group, 500 mg (5 cc) of Tranexamic Acid was administered by nebulizer and in 4 doses, and in the control group 5 cc distilled water Will not be prolonged. The results of this study included: volume and frequency of hemoptysis, the amount of invasive interventions in the two groups and the final outcome of the treatment of patients

Main outcome variables

Frequency of hemoptysis, volume of hemoptysis, the need for invasive interventions, duration of admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170313033051N2**

Registration date: **2019-03-30, 1398/01/10**

Registration timing: **prospective**

Last update: **2019-03-30, 1398/01/10**

Update count: **0**

Registration date

2019-03-30, 1398/01/10

Registrant information

Name

Mohammad Afzalimoghaddam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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afzalimoghadam@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Impact of administration of nebulized Tranexamic Acid in control of symptoms and outcome of patients with moderate and severe hemoptysis

Public title
Impact of nebulized Tranexamic Acid in control of hemoptysis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Moderate and severe hemoptysis Age above 15 years old
Exclusion criteria:
History of allergy to Tranexamic Acid Active thromboembolic event lack of consent to participate in the study

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization Patients are randomly divided into two groups of cases and controls, and after assigning the code (drug or placebo) to each patient, the administration will be done in double blinded method (physician and patient).

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, patient care physicians and outcome evaluators do not inform that administered drug is Tranexamic Acid or placebo and only the researcher is aware of the type of prescribing drug. During the analysis of the data, it is determined which participant has received the medication and which placebo.

Placebo
Used

Assignment
Parallel

Other design features
1- Administration of nebulized Tranexamic Acid 2- Using the randomization method 3- The double blindness of the study 4- The number of sample size in comparison with other studies

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.350

Health conditions studied

1

Description of health condition studied

Hemoptysis

ICD-10 code

R04.2

ICD-10 code description

Hemoptysis

Primary outcomes

1

Description

Volume of hemoptysis

Timepoint

first 48 h after admission

Method of measurement

Frequency and volume of hemoptysis (scaled container)

Secondary outcomes

1

Description

Need to invasive interventions and hospital length of stay

Timepoint

first 48 h after admission

Method of measurement

Questionnaire and hospital documents

Intervention groups

1

Description

Intervention group: Nebulizing Tranexamic Acid 500 mg (5 cc) / q12 h for 4 times

Category

Treatment - Drugs

2

Description

Control group: Nebulizing distilled water 5 cc / q12 h for 4 times

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohammad Afzalimoghaddam

Street address

Imam Khomeini Hospital, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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6th floor, Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Afzalimoghaddam

Position

Associate Profesor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Patients` data after collection, without name will be
shared.

**When the data will become available and for how
long**

2 years after data collection

To whom data/document is available

Researchers and physicians

Under which criteria data/document could be used

No condition

From where data/document is obtainable

Via e-mail

**What processes are involved for a request to access
data/document**

Studying the request and find the required information in
the existing data bank and answering during 30 business
days

Comments