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

+98 21 6690 4848

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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 committe of Tehran University of Medical Sceinces

Street address

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

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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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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