

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the amount of extraction complications of chest tubes within 48 hours and 72 hours after insertion in trauma patients at Sina Hospital

Protocol summary

Study aim

Investigating the complications of chest tube removal in the period of 48 hours after insertion and 72 hours after insertion in trauma patients of Sinai Hospital.

Design

The clinical trial has two intervention groups, single-blind, randomized, on 100 patients, block randomization list was used for randomization.

Settings and conduct

Location: Sina Hospital, context: trauma patients who candidate for chest Intubation. procedure : patients are randomly divided into two equal groups, blinding is one-way and only specialist doctors know. In the first group of patients, the chest tube is clamped for 6 hours 48 hours after implantation, and in the second group of patients, the chest tube is clamped for 6 hours 72 hours after implantation, then a simple chest X-ray is taken

Participants/Inclusion and exclusion criteria

Entry requirements: patients over 18 years old who have an indication for chest tube Exit: Death before the tube chest

Intervention groups

group 1: trauma patients after chest tube insertion and removal within 48 hours after insertion group 2: trauma patients after chest tube insertion and removal within 72 hours after insertion

Main outcome variables

pneumothorax, blood oxygen saturation, pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055031N3**

Registration date: **2023-09-04, 1402/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-04, 1402/06/13**

Update count: **0**

Registration date

2023-09-04, 1402/06/13

Registrant information

Name

Seyed Amir Miratashi Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0000

Email address

amiratashi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-14, 1402/05/23

Expected recruitment end date

2024-08-13, 1403/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the amount of extraction complications of chest tubes within 48 hours and 72 hours after insertion in trauma patients at Sina Hospital

Public title

Comparison of chest tube removal complications in trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Availability of demographic information Chest tube indication Age over 18 years Blunt trauma that caused pneumothorax

Exclusion criteria:
Death before chest tube insertion Repeated chest tube Underlying lung disease Penetrating chest trauma Presence of hemothorax

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the block randomization list, they are divided into two equal groups. The method of hiding the process of randomization of the list of random allocation of patients was only available to the clinic nurse. In order to hide the random allocation process, the sequence of treatments was written on the cards in order, then the cards were placed in sealed envelopes. A random 10-digit code was written on each envelope without any order or framework, which was the identification number of the relevant patient and only the project methodological was aware of the relevant code. When the doctor announced the eligibility of a patient, the nurse provided the envelope to the doctor and the desired treatment was carried out based on the type mentioned in the envelope. And the review of the study results was completed by the doctor who was unaware of the type of intervention. Due to the type of treatment, patients will know the type of intervention.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants do not know about being in two study groups, and the treatment is done for the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of medical faculty of Tehran University of Medical Sciences

Street address
Tehran, Tehran, intersection of Keshavarz Blvd and Qods St., headquarters building of Tehran University of Medical Sciences, 6th floor, room 604, Secretariat of Research Ethics Committee

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2023-08-12, 1402/05/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.261

Health conditions studied

1

Description of health condition studied
Complications of chest tube removal

ICD-10 code
S17.0

ICD-10 code description
Crushing injury of larynx and trachea

Primary outcomes

1

Description
Recurrence of ex tube

Timepoint
48 and 72 hours after externalization

Method of measurement
questionnaire and Visual Analogue Scale

Secondary outcomes

1

Description
Examining danger symptoms such as shortness of breath, feeling of suffocation, increase in heart rate per minute, increase in breath rate per minute, pain intensity check

Timepoint
Outcome measurement period 48 hours and 72 hours after the intervention

Method of measurement
Visual Analogue Scale, complaint questionnaire

Intervention groups

1

Description

The first intervention group: trauma patients after Intubation and chest tube removal within 48 hours after implantation.

Category

Rehabilitation

2

Description

The second intervention group: trauma patients after Intubation and chest tube removal within 72 hours after implantation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Seyed Amir Mir_Atashi

Street address

Imam Khomeini Street, Hassan Abad Square, Sina Hospital, Tehran

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Web page address

https://sinahospital.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbar Fotouhi

Street address

Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, Keshavarz Blvd., corner of Quds St.

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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

Seyed Amir Miratashi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

The entire data will be shared after unidentifying people personal data

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to perform further research with the request from the scientific institute

From where data/document is obtainable

Dear applicants will be referred to Sina Hospital's scientific Center for access to Documents and Data or the applicant can email the project executor. the email address is available. (amiratashi@sina.tums.ac.ir)

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

After receiving the letter from the project executor, the applicant can refer to Sina Hospital Research Center and after the approval of the executor, the documents and data will be available to executor within a week or the applicant can email directly to project executor so the executor provide the information

Comments