Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of pentoxifylline on the incidence rate of acute respiratory distress syndrome (ARDS) in trauma patients

Protocol summary

Study aim

Evaluating the effect of pentoxifylline administration on the incidence rate of acute respiratory distress syndrome (ARDS) in trauma patients

Design

Randomized triple-blind clinical trial on 62 patients.

Settings and conduct

The effect of pentoxifylline on the incidence of ARDS in trauma patients will be examined in Kamyab Hospital, Mashhad. Sixty-two patients were identified by an intensive care specialist who has completed the entry and exit requirements, the informed consent form is signed by the guardian and entered into the study. Patients are divided into two groups of control and intervention, based on the type of drug received. Using the allocated codes, the intervention group receives a solution of pentoxifylline for one week and the placebo group receives a placebo for one week. Blinding individuals would be patient, doctor, nurse, and analyzer.

Participants/Inclusion and exclusion criteria

Age between 18 and 65 years Trauma patients at risk for ARDS who have lips≥4 based on lung injury prediction score (lips) will be included in the study. Patients with no written informed consent, patients with adrenal insufficiency, patients with inflammation of the blood vessels, patients with intolerance to methylxanthine and pentoxifylline, patients who cannot be prescribed the drug orally, and occurrence of possible drug-related side effects if dangerous or intolerable to the patient are not included in the study.

Intervention groups

In the intervention group, patients received a suspension prepared from pentoxifylline tablets at a dose of 400mg/day in three divided doses for one week. In the placebo group, patients receive a suspension prepared from a placebo tablet as the previous method at the time of administration and in 3 separate doses per day for one week.

Main outcome variables

The incidence rate of acute respiratory distress syndrome in trauma patients

General information

Reason for update

Acronym

ARDS

IRCT registration information

IRCT registration number: **IRCT20210711051839N1**
Registration date: **2021-11-04, 1400/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-04, 1400/08/13**
Update count: **0**

Registration date

2021-11-04, 1400/08/13

Registrant information

Name

vahid jomehzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3840 0970

Email address

jomehzadehv@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-25, 1400/08/03

Expected recruitment end date

2021-11-24, 1400/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pentoxifylline on the incidence rate of acute respiratory distress syndrome (ARDS) in trauma patients

Public title

Prevention of acute respiratory problems in trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years Trauma patients at risk for ARDS who have lips≥4 based on lung injury prediction score (lips)

Exclusion criteria:

Not having written informed consent. Patients with adrenal insufficiency. Patients with inflammation of the blood vessels. Patients with intolerance to methylxanthine and pentoxifylline. Patients who can not be prescribed the drug orally. Occurrence of possible drug-related side effects if dangerous or intolerable to the patient.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Type of clinical trial: superiority, parallel, triple blinded, block randomization, allocation concealment: Sealed envelopes Generating a random allocation sequence using "www.randomization.com" for 62 people, will be done in codes A and B, and the allocation will be hidden using a blurred and numbered sealed envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

When the codes are provided and delivered to the researcher located in Kamyab Hospital, the patient is randomly placed in one of the two groups: intervention or placebo (based on the codes). The related code is recorded in the CRF form. The patient is supported by a nurse who is provided with the above form. The delivery of drugs is performed by the nurse, who is uninformed of the content of the codes and the type of pills, and the evaluator who is unaware of which drug the patient received and knows only the assigned code, performs relevant assessments. Furthermore, all patients prone to ARDS are recognized by a specified physician. After recording the history and results, the physician provides the forms to the person who analyzes the data, in the form of a code, and the data analysis is performed without the knowledge of the data analyzer of the type of drug and the content of the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Approval date

2021-05-25, 1400/03/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.141

Health conditions studied

1

Description of health condition studied

Acute Respiratory Distress Syndrome

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

Primary outcomes

1

Description

Incidence of acute respiratory distress syndrome

Timepoint

During the study and at the end of the study

Method of measurement

Diagnosis based on criteria for diagnosing acute respiratory distress syndrome

2

Description
respiration rate
Timepoint
At baseline and during the receive of the medication
Method of measurement
Cardiac Monitoring

3

Description
Heart rate
Timepoint
At baseline and during the receive of the medication
Method of measurement
Cardiac Monitoring

4

Description
continuous pulse oximetry
Timepoint
At baseline and during the receive of the medication
Method of measurement
Capnography

5

Description
Blood pressure
Timepoint
At baseline and during the receive of the medication
Method of measurement
Cardiac Monitoring

6

Description
Blood gas factors
Timepoint
At baseline and during the receive of the medication
Method of measurement
Capnography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, patients received a suspension prepared from pentoxifylline tablets at a dose of 400mg/day in three divided doses for one week.
Category
Treatment - Drugs

2

Description
Control group: In the placebo group, patients receive a suspension prepared from a placebo tablet as the previous method at the time of administration and in 3 separate doses per day for one week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamyab Hospital
Full name of responsible person
Vahid Jomehzadeh
Street address
Mashhad University of Medical Sciences, Azadi square, Mashhad, Iran
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JomehzadehV@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayour Mobarhan
Street address
Deputy of Research and Technology, Ghoreishi Building, next to Hoveyzeh Cinema, Daneshgah Street, Mashhad, Iran
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GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Jomehzadeh
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable