

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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 $lips \geq 4$ 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 \geq 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Deputy of Research and Technology, Ghoreishi Building, next to Hoveyze Cinema, Daneshgah Street, Mashhad, Iran

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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

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

Province

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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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Vahid Jomehzadeh

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Position

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Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

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

City

Mashhad

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