Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Preventive effect of pentoxifylline in Acute Respiratory Distress Syndrome susceptible children

Protocol summary

Study aim
Determining the effect of prophylactic administration of pentoxifylline in children prone to Acute Respiratory Distress Syndrome (ARDS)

Design
randomized double blind clinical trial on 40 patients. A random number table is used for randomization.

Settings and conduct
The preventive effect of pentoxifylline on the incidence of ARDS in children admitted to the PICU ward with risk factors for this disease will be investigated in Akbar Pediatric Hospital in Mashhad.In forty patients diagnosed by a pediatric intensive care specialist who have completed the entry and exit requirements, the informed consent form is signed by the guardian and entered into the study. Patients are divided into control and intervention groups based on the type of drug received using a random number table. The intervention group receives a solution of pentoxifylline for one week and the placebo group receives a placebo (water) for one week.Blinding: patient, doctor, nurse, analyzer

Participants/Inclusion and exclusion criteria
All patients at risk for ARDS who have lips≥4 based on lung injury prediction score (lips) and do not complete the ARDS diagnosis criterion will be included in the study. Children with acute perinatal hypoxemia, children with diseases that will inevitably die, children with adrenal insufficiency, and vascular inflammation are not included in the study.

Intervention groups
In the intervention group, patients received a suspension prepared from pentoxifylline tablets (tablets are administered immediately and suspended in water) at a dose of 20 mg / kg / day in three divided doses for one week. In the placebo group, patients receive a suspension prepared from a placebo tablet (a mixture of avicel-lactose) as as the previous method at the time of administration and in 3 separate doses per day for one week.

Main outcome variables
Incidence of acute respiratory distress syndrome

General information

Reason for update

Acronym
ARDS

IRCT registration information
IRCT registration number: **IRCT20190522043672N2**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-07, 1399/07/16**
Update count: **0**

Registration date
2020-10-07, 1399/07/16

Registrant information

Name
Majid Sezavar

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3870 9225

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-05, 1399/06/15

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preventive effect of pentoxifylline in Acute Respiratory Distress Syndrome susceptible children

Public title

Prevention of acute respiratory problems in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients at risk for ARDS who have lips≥4 based on lung injury prediction score (lips) and do not complete the ARDS diagnosis criteria

Exclusion criteria:

Acute prenatal hypoxemia such as premature infant-related lung disease, prenatal lung injury (such as Meconium Aspiration Syndrome, pneumonia, and sepsis occurring during childbirth) are excluded. A disease that inevitably leads to death and is contrary to life Children with adrenal insufficiency Inflammation of blood vessels Patients with intolerance to methylxanthine and pentoxifylline

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Generating a random allocation sequence using "www.randomization.com" for 40 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)

Double blinded

Blinding description

After the codes are prepared and given to the researcher located in Akbar Hospital pharmacy, the patient is randomly placed in one of the groups of intervention or placebo based on the codes.The relevant code is recorded in the CRF form.The patient is introduced to a nurse who is provided with the above form.The delivery of drugs is done by the nurse (therapist) who is unaware of the content of the codes and the type of pills, and in the meantime the evaluator (doctor) who is different from the therapist (nurse) and does not know which drug the patient received and know only the assigned code, makes relevant assessments.To increase the accuracy of the study, all patients prone to ARDS are identified 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

Shahid Kaveh Blvd., in front of Shahid Kaveh 14, Akbar Hospital, PICU

City

Mashhad

Province

Razavi Khorasan

Postal code

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Approval date

2020-07-04, 1399/04/14

Ethics committee reference number

IR.MUMS.REC.1399.317

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

3

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

6

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The suspension prepared from pentoxifylline tablets, which is administered immediately, is given orally at a dose of 20 mg / kg / day in three divided doses for one week.
Category
Treatment - Drugs

2

Description
Control group: In the placebo group, the suspension prepared from the placebo tablet (lactose avicel) is prepared at the time of administration and received in 3 divided doses per day for a week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital
Full name of responsible person
Majid Sezavar
Street address
Mashhad, Shahid Kaveh Blvd., in front of Shahid Kaveh 14, Akbar Hospital, Intensive Care Unit
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Daneshgah Street, next to Hoveyzeh Cinema, Ghoreishi Building, Deputy of Research and Technology
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Houshang Mohammadpour
Position
Associate Professor
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Other areas of specialty/work
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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