Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Studying the effect of pentoxifylline administration on the prognosis of children with community-acquired sepsis.

Protocol summary

Study aim
Studying the effect of pentoxifylline administration in patients with sepsis

Design
The clinical trial has a control group, with parallel groups, a triple-blind design, and randomization using a random number table. The patients' mortality risk assessment scores are evaluated before the intervention. Ultimately, 36 patients will be randomly assigned to two intervention and control groups.

Settings and conduct
This study will be conducted on 36 children hospitalized in the pediatric intensive care unit of Akbar Children's Hospital. After obtaining parental consent, random codes will be assigned to the patients, the codes will be recorded in the case report form, and the patients will be randomly assigned to one of the intervention or control groups. The nurse, physician, and data analyst are all unaware of the content of the codes.

Participants/Inclusion and exclusion criteria
Patient entry requirements: 1. Age range from one month to ten years 2. Children with sepsis admitted to the Akbar Intensive Care Unit with positive systemic inflammatory response syndrome in the context of a proven or probable infection Non-entry requirements: 1. History of hospitalization in the past three months or living in care facilities 2. Immunodeficiency

Intervention groups
The intervention group will receive 20 mg/kg/day Pentoxifylline, and the control group will receive an equivalent volume of water for seven days.

Main outcome variables
In all children studied, heart rate, respiratory rate, continuous pulse oximetry, and blood pressure are measured, and blood gases, inflammatory factors, length of stay in the intensive care unit, need for ventilators and vasopressors, and mortality are assessed.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190522043672N6**
Registration date: **2025-07-12, 1404/04/21**
Registration timing: **prospective**

Last update: **2025-07-12, 1404/04/21**
Update count: **0**

Registration date
2025-07-12, 1404/04/21

Registrant information

Name
Majid Sezavar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3870 9225

Email address
sezavardm@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-22, 1404/04/31

Expected recruitment end date
2026-02-19, 1404/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Studying the effect of pentoxifylline administration on the prognosis of children with community-acquired sepsis.

Public title
Studying the effect of pentoxifylline administration on the treatment of children with sepsis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A child with sepsis is admitted to the intensive care unit of Akbar Children's Hospital in Mashhad. Meets at least two of the criteria for systemic inflammatory response syndrome Age between 1month and 10 years
Exclusion criteria:
children with adrenal insufficiency lack of parental consent for the child s continued participation in the study Those who are known to be intolerant to Methylxanthines and Pentoxifylline
Age
From **1 month** old to **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize and divide patients into two groups (control and intervention), and to determine the type (interventional drug or placebo), a random number table method will be used. The table assigning each code to each patient will be provided to the researcher located in the Akbar Hospital pharmacy. It should be noted that this researcher is fully aware of the types of codes and knows which drug each patient has received. The drugs are also provided to him based on the number (A or B), and he is fully aware of which drug or placebo. This researcher is not involved in prescribing, evaluating treatment, or analyzing data and is only responsible for maintaining the codes and assigning patients to one of the relevant codes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After the codes are prepared and provided to the researcher located in the Akbar Hospital pharmacy, the patient is randomly assigned to one of the groups based on the codes. The relevant code is recorded in the Case report form. The patient is introduced to a nurse who is provided with the above form. The delivery of the drugs is done by a nurse (therapist) who is unaware of the content of the codes and the type of pills. In the meantime, the evaluator (physician), who is different from the therapist (nurse) and does not know which drug the patient received and is only aware of the assigned code, performs the relevant assessments. To increase the accuracy of the study, all patients with sepsis are identified by a physician. After recording the history and results, this physician provides the forms to the person who analyzes the data in code form, and the data analysis is also performed without the knowledge of the person analyzing the data about 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
University Street, Gharibshi Building, Vice Chancellery for Research, University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2024-09-29, 1403/07/08
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.274

Health conditions studied

1

Description of health condition studied
community acquired sepsis
ICD-10 code
A41
ICD-10 code description
Other sepsis

Primary outcomes

1

Description
heart rate
Timepoint
Daily examinations by an intensive care specialist continue for one week before the intervention begins.

Method of measurement
Monitoring Device

2

Description
respiratory rate
Timepoint
Daily examinations by an intensive care specialist continue for one week before the intervention begins.
Method of measurement
Monitoring Device

3

Description
Blood oxygen saturation
Timepoint
Daily examinations by an intensive care specialist continue for one week before the intervention begins.
Method of measurement
Pulse Oximetry

4

Description
Blood Pressure
Timepoint
Daily examinations by an intensive care specialist continue for one week before the intervention begins.
Method of measurement
Monitoring Device

Secondary outcomes

1

Description
Length of stay in the intensive care unit
Timepoint
Daily check-ups by the intensive care physician continue for one week before the intervention.
Method of measurement
Researcher-made questionnaire

2

Description
Need for a ventilator
Timepoint
Daily checks by an intensive care physician continue for one week before the intervention begins.
Method of measurement
Temporarily or permanently unable to breathe independently

3

Description
Need for a vasopressor
Timepoint
Daily checks by an intensive care physician continue for one week before the intervention begins.
Method of measurement
Monitoring device

4

Description
Mortality
Timepoint
Daily examinations by an intensive care physician continue for one week from the start of the intervention.
Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group: Patients in this group receive a suspension prepared from a 400 mg pentoxifylline tablet (the tablet is crushed at the time of administration and suspended in water) with an oral dose of 20 mg per kilogram per day, in three divided doses. The treatment continues for one week.
Category
Treatment - Drugs

2

Description
Control group: The control group will use a tablet made from Oisel and lactulose, which is completely similar to the original drug in terms of appearance and color. This drug is prepared as a suspension in water and administered to the patient.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Akbar Hospital
Full name of responsible person
Majid Sezavar
Street address
Akbar University Children's Hospital Shahid Kaveh Avenue, Near 14th Crossway
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Mashhad
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9173595100
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ak.pr@mums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Vice Chancellor for Research & Technology 3rd Floor, Mashhad University of Medical Sciences University Street, Next to Hoveizeh Cinema Mashhad, Khorasan Razavi, 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

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant professor in Mashhad University Of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor Of Mashhad University Of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

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

After the results are published in reputable scientific journals, interested parties can access the article.

When the data will become available and for how long

The period of access to results begins after the completion of the research.

To whom data/document is available

All people interested in the research topic can access the results.

Under which criteria data/document could be used

After the results are published in the form of a thesis and article, those interested in further explanations can reach the authors through the communication channels included in the article and ask their questions, and if they need raw data, they can send their request. After the research team reviews it, approval or disapproval of sending the data will be announced.

From where data/document is obtainable

To receive documentation, you can refer to the email address or phone number of the author responsible for responding.

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

After receiving a request for data/documents, the requests will be reviewed within a maximum of one week and the results will be communicated to the individuals.

Comments