Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluating the effectiveness of taurine in reducing the incidence of ventilator-associated pneumonia inchildren undergoing mechanical ventilation in the pediatric intensive care unit of Shiraz Namazi Hospital arandomized, double-blind clinical trial

Protocol summary

Study aim

The effectiveness of taurine in reducing the incidence of ventilator-associated pneumonia in children under mechanical ventilation pediatric's intensive care unit of Namazi Hospital, Shiraz: a randomized, double-blind clinical trial.

Design

A randomized clinical trial with the control group, with parallel groups, double-blind, phase 3 on 72 patients. A table of random numbers was used for randomization.

Settings and conduct

In this study, randomization is done using a table of random numbers. In a ratio of one to one, one group receives taurine 30 mg/kg in two divided doses and another group gets a placebo 30 mg/kg in two divided doses of carboxymethyl Cellulose is given. All patient information is recorded and analyzed after collection. This study will be conducted in Namazi Hospital affiliated with Shiraz University of Medical Sciences, Shiraz, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all children from 3 months to 15 years who need mechanical ventilation for more than 48 hours and the completion of the ethical consent form by their parents, exclusion criteria before randomization: malignancy, AIDS, patients with heart failure, age Less than three months, Cystic fibrosis patients

Intervention groups

Patients are randomly divided into two receiving groups: taurine or placebo (carboxymethyl cellulose) orally from the time of intubation until the patients are hospitalized in the PICU department.

Main outcome variables

The incidence rate of ventilator-associated pneumonia, The incidence of septic shock

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120731010453N4**
Registration date: **2023-06-29, 1402/04/08**
Registration timing: **prospective**

Last update: **2023-06-29, 1402/04/08**
Update count: **0**

Registration date

2023-06-29, 1402/04/08

Registrant information

Name

Mojtaba Shafiekhani

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the effectiveness of taurine in reducing the incidence of ventilator-associated pneumonia inchildren undergoing mechanical ventilation in the pediatric intensive care unit of Shiraz Namazi Hospital arandomized, double-blind clinical trial

Public title
The effect of taurine in reducing the incidence of ventilator-associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study and complete the ethical consent form by the parents. All children aged 3 months to 15 years who need mechanical ventilation for more than 48 hours.

Exclusion criteria:
Malignancy, AIDS Patients with heart failure Age less than three months Cystic fibrosis patients

Age
From **3 months** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **36**
36 patients are in the intervention group (taurine) and 36 patients are in the control group (placebo).

Randomization (investigator's opinion)
Randomized

Randomization description
All patients are randomly divided into two groups receiving taurine supplements or placebo by permutation blocking method. Quadruple permutation block randomization: All possible blocks are arranged as follows: Block 1: Block ABAB 2: Block AABB 3: Block ABBA 4: Block BBAA 5: Block BABA 6: BAAB We need 18 blocks to select 72 people. We choose these blocks randomly from numbers 1 to 6. For example, if number 6 is chosen as the first block and number 2 is chosen as the second block, the people entering the study will be given BAABAABB in that order. Finally, group A receives placebo and group B receives taurine.

Blinding (investigator's opinion)
Double blinded

Blinding description
In our study, the participants (patients) and the researcher do not know whether each patient received taurine or placebo. Taurine and placebo are both prepared in the form of 250 mg capsules with the same shape, color, and size and in the same packaging. Only one of the colleagues, who does not have a role in evaluating the results and analyzing the data, knows about the division of patients based on the table of random numbers.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz, Zand Ave, Central building of Shiraz University of medical sciences.

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2023-06-24, 1402/04/03

Ethics committee reference number
IR.SUMS.REC.1402.149

Health conditions studied

1

Description of health condition studied
Ventilator-associated pneumonia

ICD-10 code
J95.851

ICD-10 code description
Ventilator associated pneumonia

Primary outcomes

1

Description
The incidence of ventilator-associated pneumonia

Timepoint
During the intubation period of the patient in the intensive care unit

Method of measurement
Based on the criteria of ventilator-associated pneumonia (doctor's clinical suspicion, patient's tests, patient's radiograph, and culture results)

Secondary outcomes

1

Description
The incidence of septic shock
Timepoint
As long as the patient is in the intensive care unit
Method of measurement
Diagnosis and confirmation by the doctor

Intervention groups

1

Description
Intervention group: Patients receive taurine in the amount of 30 mg/kg in the form of 250 mg capsules (in two divided doses) (from Allmax Nutrition Company) until they are hospitalized in the intensive care unit.
Category
Treatment - Drugs

2

Description
Control group: Patients receive 30 mg/kg carboxymethyl cellulose in the form of 250 mg capsules (in two divided doses) (from Merck Company) until they are hospitalized in the intensive care unit.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Nasrin Shirzad yazdi
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Zand Ave, Namazi Square, Namazi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Shirzad yazdi
Position
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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
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