

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the use of albumin add-on therapy to loop diuretic for the management of pleural effusion in mechanically ventilated ill children

Protocol summary

Study aim

The aim of this study is to evaluate the effect of use of albumin add-on therapy to loop diuretic for the management of pleural effusion in mechanically ventilated ill children

Design

Two arm, double blind, parallel group clinical trial, phase 2. In this study, 50 patients between 1 to 12 years old, admitted to PICU , who have pleural effusion, will randomly be assigned in two groups of only lasix or lasix plus albumin.

Settings and conduct

This is a double blinded study on 50 patients admitted in PICU of Emam Hosein hospital of Esfahan , who have pleural effusion, and receive only lasix or lasix plus albumin and will be compared about decrease in volume of pleural effusion

Participants/Inclusion and exclusion criteria

Inclusion criteria: ICU-admitted children; Under mechanical ventilation; Diagnosis of pleural effusion; Age range of 1-12 years old; Systolic blood pressure above 100 mmHg; Serum albumin levels of less than 2.5 mg/dl.

Intervention groups

Intervention group: 1 gr/kg albumin 20% plus 2 mg/kg furosemide for three days. Control group: treatment with 2 mg/kg furosemide plus 5 ml/kg of saline 0.9% as placebo for 3 days.

Main outcome variables

Volume of pleural effusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039739N4**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

Mohammadreza Habibzadeh siahroodkolaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the use of albumin add-on therapy to loop diuretic for the management of pleural effusion in mechanically ventilated ill children

Public title

Treatment of pleural effusion by albumin and lasix

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ICU-admitted children Under mechanical ventilation
Diagnosis of pleural effusion Age range of 1-12 years old
Systolic blood pressure above 100 mmHg Serum albumin levels of less than 2.5 mg/dl

Exclusion criteria:

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization (random number table): even numbers will be allocated to control group (treatment by lasix) and odds numbers will be allocated to intervention group (treatment by Lasix and albumin)

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and evaluator of the outcomes are not aware of the kind of drugs and drugs will be provided by the researcher and will be given to the nurses for usage.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezarjerib street

City

Esfahan

Province

Isfahan

Postal code

ندارد

Approval date

2020-01-08, 1398/10/18

Ethics committee reference number

IR.MUI.MED.REC.1398.512

Health conditions studied

1

Description of health condition studied

Pleural effusion

ICD-10 code

J90

ICD-10 code description

Pleural effusion, not elsewhere classified

Primary outcomes

1

Description

volume of pleural effusion

Timepoint

Every day up to 3 days

Method of measurement

FAST sonography

Secondary outcomes

empty

Intervention groups

1

Description

Control group: treatment with furosemide (2 mg/kg; Aburaihan Company; Iran) plus 5 ml/kg of saline 0.9% as placebo for 3 days

Category

Treatment - Drugs

2

Description

Intervention group: 1 gr/kg albumin 20% (5 ml/kg; Alborzdarou; Iran) plus furosemide (2 mg/kg; Aburaihan Company; Iran) for three days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein hospital

Full name of responsible person

Mohammadreza Habibzadeh

Street address

Emam Khomeini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Habibzadeh

Position

Assistant professor

Latest degree

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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