Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of continuous versus bolus intermittent Furosemide infusion on the pulmonary status and, hemodynamic responses in neonates with congestive heart failure

Protocol summary

Study aim

Determining and comparing the effect of continuous injection versus intermittent bolus injection of furosemide on pulmonary condition and hemodynamic responses of infants with heart failure.

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment design of130 patients.

Settings and conduct

Furosemide drug in the continuous administration group will start with an initial dose of 0.1 mg per kilogram of body weight per hour, and the drug dose can be doubled every 2 hours (the maximum dose received is 6 mg per kilogram of body weight per day) in The intermittent bolus administration method, the initial dose of 1 mg per kilogram of body weight will be administered every 12 hours daily. Average pulmonary function indices and hemostatic responses will be recorded every 4 hours and then at the end of 48 hours after the start of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all infants from birth to 28 days, weight over 1000 grams, symptoms of heart failure and Symptoms of respiratory distress (tachycardia, tachypnea) will be a drop in oxygen saturation and a decrease in urinary output. Babies with an age of more than 28 days, a birth weight of less than 1000 grams, severe electrolyte disorders and the presence of shock symptoms are excluded from the study.

Intervention groups

Neonates with heart failure are randomly divided into two groups, one group is given continuous intravenous furosemide and the next group is prescribed intermittently.

Main outcome variables

Reducing the duration of heart failure treatment, electrolyte disturbances, the time of mechanical ventilation and kidney complications.

General information

Reason for update

Acronym

CHF

IRCT registration information

IRCT registration number: **IRCT20210317050737N1**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **prospective**

Last update: **2022-11-29, 1401/09/08**
Update count: **0**

Registration date

2022-11-29, 1401/09/08

Registrant information

Name

Maryam Ahmadipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of continuous versus bolus intermittent Furosemide infusion on the pulmonary status and, hemodynamic responses in neonates with congestive heart failure

Public title

Comparison of intravenous and intermittent furosemide injection on pulmonary status and heart failure of newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All term newborn boys and girls, diagnosed with heart failure

Exclusion criteria:

Neonate with an age of more than 28 days, a birth weight of less than 1000 grams, severe electrolyte disorders and the presence of shock symptoms are excluded from the study.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using a Random number table and Numbered containers in such a way that infants with heart failure with even numbers are placed in the continuous treatment group and with odd numbers in the intermittent treatment group by the resident physician.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who is responsible for collecting information and evaluating the outcome is blinded to the method of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

No. 6, Eest Zohre kermani Ave.Emam jomeh Blvd.

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Province

Kerman

Postal code

7619643781

Approval date

2022-11-13, 1401/08/22

Ethics committee reference number

1401-117

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Heart failure

Timepoint

Pulmonary function indicators and hemodynamic responses of infants will be reported every 4 hours and urinary output every 6 hours and at the end of every 48 hours after treatment with an average score.

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Treatment of heart failure

Timepoint

Pulmonary function indicators and hemodynamic responses of infants will be reported every 4 hours and urinary output every 6 hours and at the end of every 48 hours after treatment with an average score.

Method of measurement

Echocardiography

Intervention groups

1

Description
In the intervention group, continuous administration will start with an initial dose of 0.1 mg per kilogram of body weight per hour, and the drug dose can be doubled every 2 hours, with a maximum dose of 0.4 mg per kilogram of body weight.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzali pour hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Kerman 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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available