Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between efficacy of aerosolized and intravenous furosemide on oxygen requirement in 10 days preterm neonate with oxygen dependency

Protocol summary

Study aim
Comparison between efficacy of aerosolized and intravenous furosemide on oxygen requirement in >10 days preterm neonate with oxygen dependency

Design
In this study 36 preterm neonates older than 10 days who have inclusion criterieon and admitted in Hafez and Namazi hospital will be entered . After administration of aerosolized and intravenous forms of furosemide, neonate will be checked for lab data.

Settings and conduct
The neonate who admitted at Namazi and Hafez NICU wards will be selected for this study

Participants/Inclusion and exclusion criteria
Inclusion criteria: neonate with gestational age<32 week; birth weight <1500 gr; age >10 days; who are dependent to oxygen. Exclusion criteria: neonate with major congenital anomalies; cyanotic heart disease; renal disease

Intervention groups
A group of 36 neonates who will receive aerosolized for fist time and intravenous forms of furosemide for next time.

Main outcome variables
Measuring Bun, Na,K Measuring ABG Measuring ca/cr ratio in urine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140311016936N2**
Registration date: **2019-09-07, 1398/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-07, 1398/06/16**
Update count: **0**

Registration date
2019-09-07, 1398/06/16

Registrant information

Name
Fariba Hemmati

Name of organization / entity
Shiraz University Of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-21, 1397/08/30

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
2018-11-21, 1397/08/30

Actual recruitment end date
2019-10-23, 1398/08/01

Trial completion date
2019-10-23, 1398/08/01

Scientific title
Comparison between efficacy of aerosolized and intravenous furosemide on oxygen requirement in 10 days preterm neonate with oxygen dependency

Public title
Effect of aerosolized furosemide on the oxygen requirement of preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm neonates with gestational age < 32 weeks Preterm neonates with birth weight <1500gr Preterm neonates with age> 10 days Preterm neonates who require oxygen

Exclusion criteria:

Neonate with major congenital anomalies Neonate with cyanotic heart disease Neonate with renal failure disease Patient who needs corticosteroids in hospital course

Age

From **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

shiraz

Province

Fars

Postal code

34786-71946

Approval date

2018-11-18, 1397/08/27

Ethics committee reference number

IR.SUMS.MED.REC.1397.348

Health conditions studied

1

Description of health condition studied

Chronic lung disease of preterm neonates (CLD)

ICD-10 code

J70.2

ICD-10 code description

Acute drug-induced interstitial lung disorders

Primary outcomes

1

Description

Ca/Cr ratio of urine

Timepoint

Daily

Method of measurement

Laboratory measurement

2

Description

BUN ,Na, K serum

Timepoint

Before drug administration, 49 hours and 97 hours after first doses of drug

Method of measurement

Laboratory measurement

3

Description

ABG

Timepoint

Before drug administration, one hour after second and third dose

Method of measurement

Laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description

The premature neonates who had inclusion criteria were received aerosolized and intravenous furosemide, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazee hospital
Full name of responsible person
Dr.Ashkan NikAeen, Fariba Hemmati
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Namazee square, Namazee hospital
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2

Recruitment center
Name of recruitment center
Hafez Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Yoones Ghasemi
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Zand street, Building of Shiraz University of Medical Sciences, Zand Ave
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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
Ashkan Nik Aeen
Position
Neonatalogy flowship
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information and research data informed consent form: Complete the informed consent form by the patient
When the data will become available and for how long
2019 informed consent form: 2019
To whom data/document is available
Researcher & Patient informed consent form: Patient
Under which criteria data/document could be used
Informed consent form: Awareness of test results
From where data/document is obtainable
Neonatal ward Shiraz university of medical sciences informed consent form: Neonatal ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
Vice chancellery informed consent form: Vice chancellery
Comments