

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy and complication of humidified high flow nasal cannula versus nasal continuous positive airway pressure after treatment with surfactant in neonate with respiratory distress syndrome: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the efficacy and complication of humidified high flow nasal cannula versus nasal continuous positive airway pressure after treatment with surfactant in neonate with respiratory distress syndrome.

Design: A randomized clinical trial. **Setting and conduct:** The eligible neonate with respiratory distress syndrome who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 28 to 36 months; premature neonate; affecting with respiratory distress syndrome; hospitalization in NICU with 24 hours after birth. **Exclusion criteria:** Being born in other hospitals. **Intervention group:** Treatment with surfactant 200 mg/kg for one week plus continuous positive airway pressure through the nasal mask with a pressure of 4 cm water and FIO₂ equal to 40% for one week. **Control group:** Treatment with surfactant 200 mg/kg plus humidified high flow through bilateral nasal cannula with a pressure of 2 liter per minute for one week. **Primary outcome:** The need for intubation 72 hours after treatment with clinical examination. **Secondary outcome:** (a) number days required for respiratory protection 72 hours after treatment based on clinical examination; (b) duration of admission 72 hours after treatment according to medical records.

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709049014N181**
Registration date: **2017-09-07, 1396/06/16**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and complication of humidified high flow nasal cannula versus nasal continuous positive airway pressure after treatment with

surfactant in neonate with respiratory distress syndrome:
a randomized clinical trial

IR.UMSHA.REC.1396.423

Public title

Comparison of the efficacy and complication of humidified high flow nasal cannula versus nasal continuous positive airway pressure after treatment with surfactant in neonate with respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 28 to 36 months; premature neonate; affecting with respiratory distress syndrome; hospitalization in NICU with 24 hours after birth.
Exclusion criteria: Being born in other hospitals.

Age

From **7 months** old to **9 months** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Adult respiratory distress syndrome

ICD-10 code

J80

ICD-10 code description

Adult respiratory distress syndrome

Primary outcomes

1

Description

The need for intubation

Timepoint

72 hours after treatment

Method of measurement

with clinical examination

Secondary outcomes

1

Description

number days required for respiratory protection

Timepoint

72 hours after treatment

Method of measurement

based on clinical examination

2

Description

duration of admission

Timepoint

72 hours after treatment

Method of measurement

according to medical records

Intervention groups

1

Description

Intervention group: Treatment with surfactant 200 mg/kg for one week plus continuous positive airway pressure through the nasal mask with a pressure of 4 cm water and FIO2 equal to 40% for one week.

Category

Treatment - Other

2

Description

Control group: Treatment with surfactant 200 mg/kg plus humidified high flow through bilateral nasal cannula with

a pressure of 2 liter per minute for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Masoomah Mahdiankhoo

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr Masoomah Mahdiankhoo

Position

Resident of Neonate

Other areas of specialty/work

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Postal code

Phone

+98 81 3828 3939

Fax

Email

drmmahdiankhoo@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr Mayam Shokoohi Solgi

Position

Neonates Specialist

Other areas of specialty/work

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Postal code

Phone

+98 81 3828 3939

Fax

Email

drmmahdiankhoo@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty