

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Airway Pressure and HHFNC(Humidified high-flow nasal cannula) after surfactant injection in the treatment of respiratory distress in Premature neonates less than 34 weeks

Protocol summary

2018-04-04, 1397/01/15

Study aim

The aim of present study was to Compare Effectiveness of NCPAP (Nasal Positive Airway Pressure) and HHFNC (Humidified high-flow nasal cannula) after surfactant injection in the treatment of respiratory distress in premature neonates less than 34 weeks.

Design

Randomized clinical trial

Settings and conduct

This study is a randomized clinical trial that will be conducted in the NICU section of the Ayatollah Rouhani Hospital in Babol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonate neonate with respiratory distress with surfactant indication for. Exclusion criteria: Neonate with congenital heart disease; Neonate is fifth minute Apgar score of less than five.

Intervention groups

Intervention group 1: Ventilatory nasal continuous positive airway pressure Intervention group 2: Ventilatory humidified high flow nasal cannula

Main outcome variables

Response to treatment

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180226038865N1**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **prospective**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

Registrant information

Name

Avishan Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 6963

Email address

a.mohammadi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Airway Pressure and HHFNC(Humidified high-flow nasal cannula) after surfactant injection in the treatment of respiratory distress in Premature neonates less than 34 weeks

Public title

Comparison of two forms of non-invasive respiratory supporting preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria: Premature neonate with respiratory distress with surfactant indication for.

Exclusion criteria:
Exclusion criteria: infants with congenital heart disease.
Exclusion criteria: is fifth minute Apgar score of less than five.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Ganjafrooz Street

City
Babol

Province
Mazandaran

Postal code
4717647745

Approval date
2017-10-23, 1396/08/01

Ethics committee reference number
MUBABOL.HRI.REC.1396.36

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborns

ICD-10 code
p22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Response to treatment

Timepoint
Every 2 hours for 24 hours

Method of measurement
Comparing survival rates

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Ventilatory nasal continuous positive airway pressure

Category
Treatment - Devices

2

Description
Intervention group 2: Ventilatory humidified high flow nasal cannula

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Ruhani

Full name of responsible person
Zahra Akbarian Rad

Street address
Ganjafrooz Street ,Ayatollah Ruhani

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 3223 8301

Fax
+98 11 3223 8309

Email
zhr_akbarian@yahoo.com

Web page address

<http://rohani.mubabol.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr Ali Akbar Moghaddamnia

Street address

Babol University of Medical Sciences, Ganjafroz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 4727

Fax

+98 11 3219 9591

Email

info@mubabol.ac.ir

Web page address

<http://research.mubabol.ac.ir>

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Zahra Akbarian Rad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

No 19, Amirkola Children's Hospital

City

Babol

Province

Mazandaran

Postal code

4731741151

Phone

+98 11 3234 6963

Fax

+98 11 3234 6963

Email

zhr_akbarian@yahoo.com

Web page address

<http://amirkola.mubabol.ac.ir>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Zahra Akbarian Rad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

No 19, Amirkola Children's Hospital

City

Babol

Province

Mazandaran

Postal code

4731741151

Phone

+98 11 3234 6963

Fax

+98 11 3234 6963

Email

zhr_akbarian@yahoo.com

Web page address

<http://amirkola.mubabol.ac.ir>

Person responsible for updating data**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Zahra Akbarian rad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

No 19, Amirkola Children's Hospital

City

Babol

Province

Mazandaran

Postal code

4731741151

Phone

+98 11 3234 6963

Fax

+98 11 3234 6963

Email

zhr_akbarian@yahoo.com

Web page address

<http://amirkola.mubabol.ac.ir>

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

-

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