Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of nasal continuous positive airway pressure (NCPAP) therapy with combination of High-Frequency Oscillations and NCPAP in treatment of respiratory distress syndrome in infants

Protocol summary

Study aim
Comparison of the effectiveness of nasal continuous positive airway pressure (NCPAP) therapy with combination of High-Frequency Oscillations and NCPAP in treatment of respiratory distress syndrome in infants

Design
Clinical trial with control group and two arm parallel group randomised trial with blinded

Settings and conduct
The study perform in NICU Parents of neonates were kept unaware of groups their neonate was allocate to

Participants/Inclusion and exclusion criteria
infants less than 35 weeks old with RDS were enrolled.Death rate of infants during the study, chromosomal anomalies, associated severe anomalies, pulmonary disease other than RDS, congenital heart disease, IVH Grade 2 and abovewere the exclusion criteria

Intervention groups
Control group manage with nasal continuous positive airway pressure (NCPAP) and another group manage with combination of High-Frequency Oscillations and NCPAP

Main outcome variables
Hospital stay Oxygenation duration time Pneumothorax rate Pulmonary Hemorrhage rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180915041040N3**
Registration date: **2019-08-17, 1398/05/26**
Registration timing: **retrospective**
Last update: **2019-08-17, 1398/05/26**
Update count: **0**

Registration date
2019-08-17, 1398/05/26

Registrant information
Name
Roya Choopani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-08-21, 1395/05/31

Expected recruitment end date
2017-08-21, 1396/05/30

Actual recruitment start date
2016-08-22, 1395/06/01

Actual recruitment end date
2018-04-09, 1397/01/20

Trial completion date
2018-05-20, 1397/02/30

Scientific title
Comparison of the effectiveness of nasal continuous positive airway pressure (NCPAP) therapy with combination of High-Frequency Oscillations and NCPAP in treatment of respiratory distress syndrome in infants

Public title
Comparison of the effectiveness of nasal continuous

positive airway pressure (NCPAP) therapy with combination of High-Frequency Oscillations and NCPAP in treatment of respiratory distress syndrome in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infants less than 35 weeks old with RDS

Exclusion criteria:

Death of neonate Chromosomal anomaly Congenital heart defect , IVH Grade 2 and above severe anomalies

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The infants were randomly assigned to two groups using a computerized random number table as NCPAP group and NCPAP+NHFVO group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind Parents of neonates were kept unaware of groups their neonate was allocate to

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Parastar Street

City

Sharekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815874119

Approval date

2016-08-21, 1395/05/31

Ethics committee reference number

IR.SKUMS.REC.1395.291

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Time of haspitalization

Timepoint

Discharge time

Method of measurement

Number day

Secondary outcomes

empty

Intervention groups

1

Description

Control group:Nasal continuous positive airway pressure (NCPAP) therapy in neonates with RDS

Category

Treatment - Devices

2

Description

Intervention group:combination of High-Frequency Oscillations and NCPAP in treatment of respiratory distress syndrome in infants

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Roya Choupani

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr.Kamal Solati
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahr-kord 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
Shahre-kord University of Medical Sciences
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Person responsible for updating data

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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 are no information
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
No - There is not 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