

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 above were 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)

Phone

+98 38 3222 0016

Email address

choopani.r@skums.ac.ir

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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Parastar Street

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Sharekord

Province

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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

Street address

Kashani Street

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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

Full name of responsible person

Roya Choupani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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