

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of nHFO with SiPAP in the treatment of preterm infants with respiratory distress syndrome weighing less than 1500 g

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of the effect of Nasal high frequency oscillatory ventilation(nHFO) with Nasal synchronized intermittent positive airway pressure(SiPAP) in the treatment of preterm infants with respiratory distress syndrome weighing less than 1500 g

Design

The clinical trial, with parallel groups, non randomized, single-center trial, sample size 60 people.

Settings and conduct

Amir Al-Momenin Hospital. Patients will be treated with either SiPAP or nHFO according to the protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants with a diagnosis of respiratory distress syndrome; Weight less than 1500 g; No prenatal asphyxia. Exclusion criteria: Patients with congenital anomalies.

Intervention groups

Intervention group 1: In the nHFO group, according to the protocol, infants with Bi nasal prong and CNO device (Medin company) are subjected to non-invasive mechanical ventilation by oscillation and periodic opening and closing of the air outlet valve. Intervention group 2: In the SiPAP group, according to the protocol, the IFD (Viasys Healthcare) injector is installed with a prong suitable for the baby and is subjected to this intervention using the SiPAP (Viasys Healthcare) support system. The Graseby capsule is placed between the umbilicus and the xiphoid appendage.

Main outcome variables

Oxygen receive the time, Duration of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N65**

Registration date: **2021-05-05, 1400/02/15**

Last update: **2021-05-05, 1400/02/15**

Update count: **0**

Registration date

2021-05-05, 1400/02/15

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nHFO with SiPAP in the treatment of preterm infants with respiratory distress syndrome weighing less than 1500 g

Public title

Comparison of the effect of Nasal high frequency

oscillatory ventilation(nHFO) with Nasal synchronized intermittent positive airway pressure(SiPAP) in the treatment of preterm infants with respiratory distress syndrome weighing less than 1500 g

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infants with a diagnosis of respiratory distress syndrome
Weight less than 1500 g No prenatal asphyxia

Exclusion criteria:

Patients with congenital anomalies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.SEMUMS.REC.1399.338

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

Oxygen receive time

Timepoint

Before the intervention and 1 week after the intervention

Method of measurement

Clinical examination (Number of days of receiving oxygen)

2

Description

Duration of treatment

Timepoint

Before the intervention and 1 week after the intervention

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the nHFO group, according to the protocol, infants with Bi nasal prong and CNO device (Medin company) are subjected to non-invasive mechanical ventilation by oscillation and periodic opening and closing of the air outlet valve.

Category

Treatment - Devices

2

Description

Intervention group 2: In the SiPAP group, according to the protocol, the IFD (Viasys Healthcare) injector is installed with a prong suitable for the baby and is subjected to this intervention using the SiPAP (Viasys Healthcare) support system. The Graseby capsule is placed between the umbilicus and the xiphoid appendage.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Navid Danaei

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Navid Danaie

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Infants

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Navid Danaie

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Infants

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Seyedeh Niloufar Amir Khalili

Position

Student

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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