Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparing the effectiveness of establishing continuous positive airway pressure through RAM cannula with nasal mask and nasal prong in newborns admitted to neonatal intensive care unit

Protocol summary

Study aim

Comparison effectiveness of establishing continuous positive airway pressure through RAM cannula with nasal mask and nasal prong in newborns admitted to neonatal intensive care unit

Design

clinical trial, 3 groups, 90 infants, block randomization allocation, R software

Settings and conduct

Shahid Beheshti & Al-Zahra Hospitalsm Isfahan University of Medical Sciences, with consent from the parents, 90 infantsm, randomized 3 groups, continuous positive airway pressure treatment with RAM cannula, nose mask & nasal prongs (30 each). Gastric tube inserted to prevent dilatation. Babys mouths were not closed. Educational package including basic method of care prepared. Checklists & questionnaires including demographic information form of newborns, mothers, efficiency & effectiveness checklist of intervention, checklist of nasal injuries & the nurses opinion about ease work with three types of interfaces.

Participants/Inclusion and exclusion criteria

age 28-34 weeks needing positive airway pressure; Apgar more than 6 minutes; No congenital malformations; or lips and nose wounds Parental consent; Nurses; bachelor's degree; one year working in the special department for babies; Infant discharge: death; Change the interface; Endotracheal intubation; Resuscitation; Parents lack of consent to continue; Referral to another hospital; Nurses: Unwillingness to cooperate; Failure to answer questionnaire; Changing place of work

Intervention groups

infants with RAM cannula, infants with nasal prongs, infants with nasal mask directly connected to the ventilation circuit with continuous positive pressure Bubble model airways

Main outcome variables

continuous positive airway pressure via RAM cannula, nasal prong and nasal mask studying the effectiveness, nasal injury, nurses view of the ease of working with three types interfaces.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230807059068N1**
Registration date: **2023-09-14, 1402/06/23**
Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**
Update count: **0**

Registration date

2023-09-14, 1402/06/23

Registrant information

Name

Zeinab Keshavarzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3782 0696

Email address

z.keshavarzian1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of establishing continuous positive airway pressure through RAM cannula with nasal mask and nasal prong in newborns admitted to neonatal intensive care unit

Public title
Comapring the effectiveness of establishing continuous positive airway pressure through RAM cannula with nasal mask and nasal prong in newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Babies born with a gestational age of 28-34 weeks Need to connect to continuous positive airway pressure within the first hour of birth Apgar more than 6 in the fifth minute Absence of congenital malformation including nasal obstruction or severe upper airway malformation such as Cowan's atresia, cleft lip and palate, congenital diaphragmatic hernia, cardiac anomalies, tracheoesophageal fistula, Pierre-Robin sequence Absence of wounds or lesions in the nose and upper lip of the baby Consent of parents of infants to participate in the study Having at least a bachelor's degree in nursing At least one year of clinical experience in neonatal intensive care unit
Exclusion criteria:
Death of a baby Changing the type of respiratory interface The baby needs endotracheal intubation The baby needs resuscitation Parents' unwillingness to continue the treatment process Referral of the baby to another hospital during the study Unwillingness of nurses to continue cooperation Failure to answer questionnaire questions Changing the place of clinical activity to another department during the study
Age
From **196 days** old to **238 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
90 infants participating in the study will be subjected to continuous positive airway pressure treatment with RAM cannula (30 people), nasal mask (30 people) and nasal prongs (30 people) in three groups using block randomization method. Six are used. All blocks are the same size. Within each block of 6, two people are randomly assigned to group A, two people to group B, and two people to group C. 15 blocks of 6 are used for this study. The software used for block allocation is R software. Blockrand Package is used in this software. Randomization of six permutation blocks, all possible blocks are arranged as follows Block 1: ABCABC, Block 2: AABBCC, Block 3: ABCCBA, Block 4: CCBBAA, Block 5: CBACBA, Block 6: CBAABC To select 90 people, we randomly select 15 blocks from numbers 1 to 6. Using R software, we choose a random number between 1 and 6. For example, if number 6 is selected as the sixth block and number 2 is selected as the second block, the people entering the study will be given CBAABCAABBCC respectively. Finally, group A received the intervention of short nose cannula, group B received the nasal mask intervention, and group C received the RAM cannula intervention through connection to the system. After study completion, intervention data for each group can be added to the data frame for analysis. Each intervention is written on a card and the cards are sealed in envelopes, then when a new person enters the study, the next envelope is opened and the sample is assigned to the corresponding treatment.
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
Isfahan University of Medical Sciences
Street address
Esfahan University of Medical Sciences, Hezar Jarib St., Isfahan, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-09-03, 1402/06/12
Ethics committee reference number
IR.MUI.NUREMA.REC.1402.092

Health conditions studied

1

Description of health condition studied

Comparing the effectiveness of establishing continuous positive airway pressure through RAM cannula with nasal mask and nasal prong in newborns admitted to neonatal intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean success and failure of continuous positive airway pressure

Timepoint

From the start of the intervention for 72 hours

Method of measurement

A researcher-made checklist for the effectiveness of continuous positive airway pressure

Secondary outcomes

1

Description

Frequency distribution of nose injuries

Timepoint

During the study

Method of measurement

Nose injury checklist

2

Description

Average satisfaction score of nurses

Timepoint

Immediately after the intervention

Method of measurement

A researcher-made questionnaire of nurses' views on the ease of doing work with three types of respiratory interfaces

Intervention groups

1

Description

Intervention group:Babies treated with RAM cannula: Babies in this group are supported by a Neotech RAM cannula of the right size according to the manufacturer's instructions, which is properly fixed on the baby's face and is directly connected to the continuous positive airway pressure circuit.

Category

Treatment - Devices

2

Description

Control group1: Control group: group supported by nasal prongs: infants in this group are supported by Medin nasal prongs with the appropriate size (according to the manufacturer's recommendations) whose prongs are directly attached using Mini flow and rubber bands that are placed on Medin caps with the appropriate size (according to the manufacturer's recommendations) are connected to the continuous positive pressure circuit of the airways.

Category

Treatment - Devices

3

Description

Control group2: Nasal mask supported group (second control group): Babies in this group are supported by Medin model nasal mask with the right size, which is connected to the positive pressure circuit using Mini flow and rubber bands on caps with Medin model with the right size (according to the manufacturer's recommendations). Continuous airways are connected and placed

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ayatollah Beheshti Hospital

Full name of responsible person

Zeinab Keshavarzian Kelishadi

Street address

Isfahan, Pol Felezi Bridge, Beginning of Motahari St

City

Isfahan

Province

Isfehan

Postal code

81848 53541

Phone

+98 31 3234 6338

Email

z.keshavarzian1992@gmail.com

2

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Zeinab Keshavarzian Kelishadi

Street address

Isfahan Province, Isfahan, Soffeh Blvd, JM53+M3J,

City

Isfahan

Province

Isfehan

Postal code

81746 75731

Phone

+98 31 3620 2020

Email
z.keshavarzian1992@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Esfahan University of Medical Sciences, Hezar Jarib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3060
Email
askari@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Keshavarzian kelishadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No 1. Andisheh A1 CPLX, Shafagh Blvd. Esfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8456119488
Phone
+98 31 3782 0696
Email
z.keshavarzian1992@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Keshavarzian Kelishadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No 1. Andisheh A1 CPLX, Shafagh Blvd. Esfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8456119488
Phone
+98 31 3782 0696
Email
z.keshavarzian1992@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Keshavarzian Kelishadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No 1. Andisheh A1 CPLX, Shafagh Blvd. Esfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8456119488
Phone
+98 31 3782 0696
Email
z.keshavarzian1992@gmail.com

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

Informed Consent Form
Undecided - It is not yet known if there will be 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