Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of skin care program on maintenance of nasal skin integrity in preterm infant that ventilated with nasal continuous positive airway pressure.

Protocol summary

Summary

The aim of study is the effect of skin care program on maintenance of nasal skin integrity in preterm infant treated with nasal continuous positive airway pressure. Design of this study is a semi-experimental and study population includes 110 preterm neonates with gestational age 28-36 weeks that admitted in neonatal intensive care unit and ventilated with nasal continuous positive airway pressure. Participated neonates are will divided to 2 groups (control, intervention). Neonates in control group will receive routine care but in the intervention group neonates will cared with new nasal skin care plan since ventilated with nasal continuous positive airway pressure until separation from device. Nasal skin care include gently massage the nasal septum and bridge of the nose every 6 hours for 2 minutes, rotation between nasal prong and mask every 6 hours, rubbing the hydro-gel to nasal septum and philtrum until weaning from nasal continuous positive airway pressure and use of tetracycline 1% ointment in erythematosus tissue. Daily nasal skin integrity and nasal skin damage intensity will evaluate and compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411054617N11**
Registration date: **2015-02-08, 1393/11/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-08, 1393/11/19

Registrant information

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Mahnaz Jabraeili
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of skin care program on maintenance of nasal skin integrity in preterm infant that ventilated with nasal continuous positive airway pressure.

Public title

The effect of skin care program on maintenance of nasal skin integrity in preterm infant that ventilated with nasal continuous positive airway pressure.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 28-36 weeks;

neonates with respiratory distress syndrome; receiving positive pressure oxygen through a nasal mask or prong; no congenital skin diseases; don't have congenital abnormalities in the nose; no immune system defect; parent consent for participation of infant in the study. Exclusion criteria: intubation of newborn during the study; unwillingness of parents to continuing of study.

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Not randomized

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
Deputy of research, Tabriz University of Medical Sciences

Street address
Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz

City
Tabriz

Postal code

Approval date
2014-12-06, 1393/09/15

Ethics committee reference number
93131

Health conditions studied

1

Description of health condition studied
Relation of skin care program with maintenance of nasal skin integrity in preterm infant that ventilated with nasal continuous positive airway pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Maitenance of Nasal skin integrity

Timepoint
Since the start of ventilation with nasal continuous positive airway pressure until occurrence skin injury, daily.

Method of measurement
By completion the Lane and Drost skin integrity scale until occurrence skin injury

Secondary outcomes

1

Description
Nasal skin injury intensity

Timepoint
Since occurrence of skin injury until weaning of device, daily.

Method of measurement
Use of nasal injury intensity scale

Intervention groups

1

Description
Infants in the control group will receive routine care which is common in that unit. Routine care includes using prong and mask with appropriate size for nares and rubbing Mupirocin ointment to nasal septum and philtrum.

Category
Prevention

2

Description
Intervention group: gently massage of the nasal septum and bridge of the nose for 2 minutes every 6 hours, rotation between nasal prong and mask every 6 hours, rubbing the hydro-gel to nasal septum and philtrum twice a day until weaning from nasal continuous positive airway pressure device and using tetracycline 1% ointment on erythematous tissue instead of hydro-gel.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Educational Center Affiliated Medical Sciences

of Tabriz, Iran

Full name of responsible person
Sakineh Karimipoor

Street address
Bagshomal Square, Tabriz, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of research, Tabriz University of Medical Sciences

Full name of responsible person
Mahnaz Jabraeili

Street address
Department of Pediatric Nursing, Nursing and Midwifery Faculty, Tabriz

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Deputy of research, Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Science

Full name of responsible person
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Position
MSc, Faculty member

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty