

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 erythematous 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

Name

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 ,Golgashst 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

Maintenance 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

Mahnaz Jabraeili

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