

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of Evidence -Based caring for Prevention of Nasal trauma in Neonates Receiving Noninvasive Mechanical Ventilation

Protocol summary

Summary

Purpose: Nasal trauma is one of the common complications of noninvasive mechanical ventilation in newborns who are receiving noninvasive Mechanical Ventilation with nasal devices Continuous positive airway pressure (nCPAP). The aim of this study is to evaluate the efficiency of Evidence -Based caring for prevention of nasal trauma in neonates receiving nCPAP

Materials and methods: In this clinical trial, 60 newborns will be considered as two groups of usual care and cares based on Evidence -Based clinical guideline consist of before and after care. In usual care group research's data will be collected by Assessment the checklist of care and examination of the nose trauma with taking pictures from the injury and inscribes number of the file (hospital records) and date of the examination in the document. And in the evidence-based care group, after providing evidence-based clinical guideline and teach it to the neonatal intensive care unit nurses, care should be based on clinical guideline in the field of of taking cars of non-invasive mechanical ventilation for infant will be considered. And then check the status of the care of infants with non-invasive mechanical ventilation checklist of care and after reaching optimal care conditions, sampling of evidence-based care group begins. Severity of nose trauma is divided in three groups of mild(erythema and erosion , moderate(ulceration and bleeding) and severe(necrosis). And the size of the damage will be compared based on the number of affected areas of the nose in the two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110824925N1**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Somayeh Pournajaf

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3221 7421

Email address

pournajafs1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Evidence -Based caring for Prevention of Nasal trauma in Neonates Receiving Noninvasive Mechanical Ventilation

Public title

Effect of Evidence -Based caring for Prevention of Nasal trauma in Neonates Receiving Noninvasive Mechanical Ventilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: nCPAP treatment. Exclusion criteria : nCPAP treatment duration lower than 24 h; upper airway malformations ; patients referred from other centres after more than 24 h of nCPAP treatment.

Age

To 2 months old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Mashhad University of Medical Science

Street address

Daneshgah st

City

Mashhad

Postal code

Approval date

2014-01-11, 1392/10/21

Ethics committee reference number

920830

Health conditions studied

1

Description of health condition studied

pressure sore

ICD-10 code

L89.9

ICD-10 code description

Decubitus ulcer and pressure area, unspecified

Primary outcomes

1

Description

prevention of nasal injury in newborn

Timepoint

daily

Method of measurement

inspection and take photos of nasal injury

2

Description

Reducing the Severity of the nose injury

Timepoint

daily

Method of measurement

inspection and take photos of nasal injury

3

Description

Reducing the size of the nose injury

Timepoint

daily

Method of measurement

inspection and take photos of nasal injury

Secondary outcomes

empty

Intervention groups

1

Description

in intervention group: use of Evidence -Based clinical guideline and then Assessment the checklist of care and examination of the nose trauma with taking pictures from the injury and inscribes number of the file (hospital records) and date of the examination in the document.

Category

Prevention

2

Description

Assessment the checklist of care and examination of the nose trauma with taking pictures from the injury and inscribes number of the file (hospital records) and date of the examination in the document.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommul-Banin hospital

Full name of responsible person

Somayeh Pournajaf

Street address

College Of Nursing and Midwifery, Doctora Crossroads

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Somayeh Pournajaf

Street address

Daneshgah st, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Somayeh Pournajaf

Position

nurse

Other areas of specialty/work

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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