Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 guidline and teach it to the neonatal intensive care unit nurses, care should be based on clinical guidline 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)
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+98 51 3221 7421
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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 referredfrom 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 Scince
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
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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
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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Person responsible for scientific inquiries

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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