Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

effects of earmuff on physiologic and dynamic responses of premature neonates admitted in neonatal intensive care unit at 2012

Protocol summary

Summary

The aim of this study is to measure impact of using the earmuff on physiologic and dynamic responses of premature infants. Main inclusions criteria are gestational age over 28 weeks and under 37 weeks and, and absence of auditory and congenital disorders and principal exclusion criteria are discharging of neonate during using muff and disagreement of parents of participate in study. Premature neonates admitted in Beheshti hospital neonatal intensive care unit with inclusion criteria are sample of the study. All participants were divided in to two groups randomly 32 in each group. The group receiving earmuff intervention was compared to the control group receiving only routine care. In this clinical trial earmuffs were placed over the premature neonate’s ears 2 hours in the morning and evening for 2 days in row to reduce noise intensity in the busiest time of neonatal intensive care unit. Using of earmuff reduce the noise intensity and will make better environment for them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092010812N2**
Registration date: **2012-10-16, 1391/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-16, 1391/07/25

Registrant information

Name

Zahra Abdeyazdan

Name of organization / entity

Isfaha University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2908

Email address

marofi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

research center of Isfahan University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effects of earmuff on physiologic and dynamic responses of premature neonates admitted in neonatal intensive care unit at 2012

Public title

Using earmuff for premature infant

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: GA more than 28 weeks and less than 37 weeks; neonates without hearing loss or any difficult on middle and external ear; no congenital problems; Apgare score more than 7; in neonate with acute respiratory distress syndrome haveing score less than 5
exclusion criteria: neonate discharge of neonatal intensive care unit; acute respiratory distress syndrome

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Unevrsity of Medical Siences

Street address

Isfaha University of Medical Siences, Hezargarib st, Isfahan

City

Isfahan

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

390623

Health conditions studied

1

Description of health condition studied

prematurity

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation. Prematurity NOS

Primary outcomes

1

Description

physiologic responsess

Timepoint

3 hours in the morning and 3 hours in the evening for 2 days in row every 15 minutes bigining 15 minute before the study and will continue 1 houre after remove the muff

Method of measurement

bservation

2

Description

dynamicl responsess

Timepoint

3 hours in the morning and 3 hours in the evening for 2 days in row every 15 minutes bigining 15 minutes befor of using ear muff and will continue until 1 hours after the remove the muff

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

earmuff will place over the premature infants ear in trial group 2 hours in the morning and 2 hours in the evening for 2 days

Category

Other

2

Description

only routine care in neonate admitted in control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti hospital

Full name of responsible person

Sara Ghassemi

Street address

shahid Beheshti Hospital, Shahid Beheshti st.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mis Keyanpour
Street address
Isfahan University of Medical Sciences, Hezargarib st, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Maryam Marofi
Position
Academic member of Faculty of Nursing and Midwifery
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 31 1792 2908
Fax
Email
marofi@nm.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfaha university of medical siences
Full name of responsible person
Zahra Abdeyazdan
Position
assistant professor
Other areas of specialty/work
Street address
Isfaha university of medical siences
City
Isfahan
Postal code
Phone
+98 31 1792 2908
Fax
Email
abdeyazdan@nm.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Sara Ghassemi
Position
master nursing student
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 31 1375 1517
Fax
Email
s.ghassemi29@yahoo.com
Web page address

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