Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of earmuffs on the physiologic and behavioral responses in preterm infants

Protocol summary

Summary

purpose: evaluate effectiveness of earmuff on the physiologic and behavioral responses in preterm infants. The study population: premature infant less than 37 gestational age. inclusion criteria: preterm infant, age more than 7 day, need to care in incubator, without congenital ear infections and other congenital anomaly. exclusion criteria: infant death, life threatening emergency condition. study sample size 36 infants. methods: a crossover study comprising 36 clinically preterm infant less than 37 gestational age cared in closed incubator was conducted. preterm infant acted as their own controls whereby they were observed without earmuff(group 1) for 1 day and with earmuff(group2) on consecutive 1 day. preterm infants physiologic responses such as blood pressure, body temperature, respiratory rate, heart rate, oxygen saturation and Anderson behavioral state scoring system scores were assessed over 30 s every 2 hour for 8 h during daytime for 2 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020817972N6**
Registration date: **2015-05-17, 1394/02/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-17, 1394/02/27

Registrant information

Name

Zahra Godarzi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Deputy for Research Tehran University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of earmuffs on the physiologic and behavioral responses in preterm infants

Public title

the effect of earmuff on the preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: preterm infant, age more than 7 day, need to care in incubator, normal audiometry, oral nutrition, no needs to use Anticonvulsants and Respiratory stimulant drugs, without congenital ear infections and other congenital anomaly, The absence of hemodynamic instability during the first week after birth, without intra ventricular hemorrhage, exclusion criteria: infant death, life threatening emergency condition,

refuse parents to participate in the study

Age
From **8 days** old to **29 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee in research Tehran University Of Medical Sciences

Street address
Room 501، Fifth Floor، Medical Ethics and History of Medicine Reserch Center، Junction of Qhods st and Keshavarz Boulvard

City
tehran

Postal code

Approval date
2014-03-15, 1392/12/24

Ethics committee reference number
7659

Health conditions studied

1

Description of health condition studied
preterm infant

ICD-10 code
p07

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.

Primary outcomes

1

Description
respiratory rate

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
respiratory rate per min measured by monitor

2

Description
heart rate

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
heart rate per min measured by monitor

3

Description
oxigen saturation

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
with palsoximeter

4

Description
body tempreture

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
santigrade degree

5

Description
sistolic blood presure

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
mmhg

6

Description
diastolic blood presure

Timepoint
Q2h with earmuff and without earmuff

Method of measurement
mmhg

7

Description
behavioral response

Timepoint
Q2h with earmuff and without earmuff

Method of measurement

abss score system

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: one day preterm infant with earmuff and one day without earmuff
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliasghar Hospital
Full name of responsible person
Doctor Nasrin Khalesi
Street address
Zafar Street، Aliasghar Hospital.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research Tehran University Of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Room 604، Sixth Floor، Central Organization Of Tehran University Of Medical Sciences، Qhods St، Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research Tehran 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University Of Medical Siences School Of Nursing And Midwifery
Full name of responsible person
Zahra Godarzi
Position
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Person responsible for updating data

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Tehran University Of Medical Science
Full name of responsible person
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Student Of Neonatal Intensive Care Nursing
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