

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

+98 21 6105 4407

Email address

godarziz@tums.ac.ir

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 Boulevard

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 Sciences School Of Nursing And Midwifery

Full name of responsible person

Zahra Godarzi

Position

Faculty Member of Nursing School

Other areas of specialty/work

Street address

Eastern Nosrat St, Doctor Mirkhani St, Tohid Square

City

Tehran

Postal code

Phone

00

Fax

Email

godarziz@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University Of Medical Science

Full name of responsible person

Azadeh Ranjbar

Position

Student Of Neonatal Intensive Care Nursing

Other areas of specialty/work

Street address

Haghighoo Avenue, Shishegaran Street.

City

Lahijan

Postal code

4418744871

Phone

+98 13 4223 6735

Fax

Email

ranjbarazadeh@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