

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of two methods of Light Reduction on Preterm Infants' Sleep in the NICU: Randomized Control Clinical Trial

Protocol summary

Summary

The purpose of this study was to determine Effect of two methods of Light Reduction in the sleep rate of premature infants in the NICU, a randomized Control clinical trial. After obtaining informed consent from parents, 60 eligible preterm infants randomly were assigned to the intervention and control groups. Routine light reduction including turn off the lights and draw the curtains of the windows will run from 19 to 7 am was administrated. In the intervention group after decreased routine light, baby incubator covered with thick cover and infant face covered with thin cover. In the control group, addition to routine light reduction, only incubator newborn covered with thin cover, but baby face not covered with anything. One of researcher recorded the infants' activities such as baby position, oxygen intake, sleeping, waking, cry and eating on a sleep diagram, once a first day and again after the 4 day of both groups by watching the 24 hours video- taped by first camera. A sleep diagram is a column to record 24 hours activities such as sleeping, waking, or feeding, or crying, and the length which is used in 20-minute intervals. Data such as gestational age, birth weight, sex, clinical diagnosis, HR, oxygen rate, type of nutrition and its volume these subjects were obtained from the clinical charts of the hospital , infants' environment light by using a lux meter and sound level by the level meter by coworker measured daily.

General information

Acronym

Effect of Light Rate Reduction on Preterm Infants' Sleep

IRCT registration information

IRCT registration number: **IRCT201409114613N13**

Registration date: **2015-01-08, 1393/10/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

Sousan Valizadeh Dehkharghani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

009804134751706- 34796770

Email address

valizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-28, 1393/10/07

Expected recruitment end date

2015-04-25, 1394/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of two methods of Light Reduction on Preterm Infants' Sleep in the NICU: Randomized Control Clinical Trial

Public title

Effect of two methods of Light Reduction on Preterm Infants' Sleep

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: 32-28 weeks gestational age preterm infants with congenital hypothyroidism and congenital brain; does not have a vision problem; taking medications affecting sleep; not receiving mechanical ventilation; not phototherapy; the lack of painful procedures on newborn infants for at least an hour before the measure sleep. Exclusion criteria: baby requiring Phototherapy ; mechanical ventilation ; intraventricular hemorrhage; necrotizing enterocolitis; patent ductus arteriosus; a blood culture positive sepsis; acute lung disease

Age
 From **7 days** old to **8 days** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **54**

Randomization (investigator's opinion)
 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
 Deputy of Research, Tabriz University of Medical Sciences

Street address
 Deputy of Research, Tabriz University of Medical Sciences

City
 tabriz

Postal code

Approval date
 2014-11-24, 1393/09/03

Ethics committee reference number
 93129

Health conditions studied

1

Description of health condition studied

Preterm Infants' Sleep

ICD-10 code

P07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description

Preterm Infants' Sleep

Timepoint

First and fifth study during 24 hours

Method of measurement

sleep diagram

Secondary outcomes

1

Description

Light rate

Timepoint

First birthday, fifth birthday, and after the intervention

Method of measurement

Luxmeter device, Model Light Meter YK-10LX

2

Description

Sector and the incubator volume system by Sound Level Meter

Timepoint

for four days , twice per day: 6pm and 4am

Method of measurement

Sound Level Meter device, Model EXTECH401027

Intervention groups

1

Description

After obtaining informed consent from parents, 60 eligible preterm infants randomly were assigned to the intervention and control groups. In the intervention group, in addition to routine light unit, baby incubator, covered with thick cover and infant face, covered with thin cover.

Category

Other

2

Description

After obtaining informed consent from parents, 60 eligible preterm infants randomly were assigned to the intervention and control groups. In the control group, in

addition to routine light unit, baby incubator, covered with thin cover and infant face, will not be covered.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Farinaz Saeidi

Street address

Al-Zahra Hospital, Artesh Hospital, Baghshmal Crossroads, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

The Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences (TUOMS).

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Sousan Valizadeh

Position

Associate Professor /PhD in Nursing

Other areas of specialty/work

Street address

Nursing And Midwifery Faculty , Tabriz University of Medical Sciences T

City

Tabriz

Postal code

51668-44199

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+98 41 3479 6770

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Email

valizades@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

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