Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effect of ambient lighting on heart rate and blood oxygen saturation in preterm infant admitted to neonatal intensive care unit in Babol, Iran

Protocol summary

Summary

The aim of the study: the effect of ambient lighting on heart rate and blood oxygen saturation in preterm infants in the NICU. Performing study design: non-random Studied mass population: 40 premature infants hospitalized in subordinate hospitals of Babol city. Inclusion criteria: premature infants less than 37 weeks; weighing less than 2500 grams; without the need for mechanical ventilation and oxygen therapy; arterial oxygen saturation in normal range. Exclusion criteria: existence of neurological- vision problems; congenital anomalies; sepsis; gastro - intestinal tract problems; congenital heart disease; respiratory distress syndrome with more or equal to 5; maternal drug addiction; drugs affecting on heart rate and arterial oxygen saturation percentage; infants undergoing phototherapy in the hospital and suffering invasive procedures. Brightness severity through the luxury meter units, recording heart rate and blood oxygen saturation in preterm infants by Saadat monitor was measured, infants at a certain time from 12:00 to 13:00 (routine based) the amount of brightness was recorded by luxury meters every 5 minutes and then the heart rate and blood oxygen saturation in the monitor display will be registered. On the same day, for the same child, between the hours of 14: 30-15:30 brightness reached 10 luxuries and we record its effect on heart rate and oxygen saturation every 5 minutes during the intervention. The primary outcome: the ambient lighting, heart rate, blood oxygen saturation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051217669N1**
Registration date: **2014-06-23, 1393/04/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-06-23, 1393/04/02

Registrant information

Name
Saide Manochehri
Name of organization / entity
Babol University of Medical Science.
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

personal.

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-04-19, 1393/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ambient lighting on heart rate and blood oxygen saturation in preterm infant admitted to neonatal intensive care unit in Babol, Iran

Public title

The effect of ambient lighting in preterm infant

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: premature infants less than 37 weeks; weighing less than 2500 grams; without the need for mechanical ventilation and oxygen therapy; arterial oxygen saturation in normal range. Exclusion criteria: existence of neurological- vision problems; congenital anomalies; sepsis; gastro - intestinal tract problems; congenital heart disease; respiratory distress syndrome with more or equal to 5; maternal drug addiction; drugs affecting on heart rate and arterial oxygen saturation percentage; infants undergoing phototherapy in the hospital and suffering invasive procedures.

Age
From **5 days** old to **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Research and Technology، Ganjafroz Street Babol university of Medical Science، Babol، Mazandaran، Iran.

City
Babol

Postal code

Approval date
2013-12-03, 1392/09/12

Ethics committee reference number
3461 /30/ژ/پ

Health conditions studied

1

Description of health condition studied
Effect of ambient lighting on heart rate and blood oxygen saturation in preterm infant

ICD-10 code
P07.3

ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Ambient lighting

Timepoint
Before and during intervention every 5 minutes to an hour

Method of measurement
In terms of luxury and using luxury meter device

2

Description
Hear rate

Timepoint
Before and during intervention every 5 minutes to an hour

Method of measurement
In terms of beats per minute using Monitor

3

Description
Blood oxygen saturation

Timepoint
Before and during intervention every 5 minutes to an hour

Method of measurement
In terms of percentage using Monitor

Secondary outcomes

1

Description
Gestational age

Timepoint
After birth

Method of measurement
In terms of day and week using Ballard scale.

2

Description
Weight

Timepoint
After birth

Method of measurement
In terms of gram using Balance

Intervention groups

1

Description

In this study, gestational age was calculated by Ballard scale and intensity of brightness in the NICU through a device called a luxury meter with 3% ± confidence level in Taiwan, heart rate and oxygen saturation percentage in preterm infants by Saadat monitor, made in Iran was measured. In order to record data on the monitor, we use the probe including a light detector, put against each other and also the tissue layers (fingers of hand or foot) and also between them. In order to get demographic information, we use birth records after attracting personnel and explaining to the parents and getting consent from them. According to selected Infants at the same time from 12:00 to 13:00 on a routine part, amount of brightness have been estimated and recorded by luxury meter and then we record heart rate and arterial oxygen saturation percentage displayed on the monitor every 5 minutes. On the same day, on the same infant from 14:30 to 15:30, amount of brightness through controlling light by covering the incubator and putting the cover on the window with the blinds and turning off non-essential lights reached 10 luxuries and then we record their effect on heart rate and arterial oxygen saturation percentage every 5 minutes during the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kola Children's Hospital

Full name of responsible person

Mr.Doctor Mousa Ahmadpour.

Street address

Research Institute of children Non Communicable Diseases، Amir Kola Children's Hospital Babol، Mazandran، Iran.

City

Babol

2

Recruitment center

Name of recruitment center

Babol Clinic

Full name of responsible person

Mr.Doctor Yadollah Zahed Pasha

Street address

Babol Clinic Hospital، Babol، Mazandran، Iran.

City

Babol

3

Recruitment center

Name of recruitment center

Shahid Ayatollah Rouhani Hospital

Full name of responsible person

Mrs.Doctor Akbarian

Street address

Shahid Ayatollah Rouhani Hospital، Gangafroze Street، Babol، Mazandran، Iran.

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences.

Full name of responsible person

Mr.Doctor Yadollah zahed pasha.

Street address

Research and Technology، Babol University of Medical Sciences، Ganjafroz street، Babol، Mazandran، Iran.

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Babol 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

Babol University of Medical Sciences.

Full name of responsible person

Mr.Doctor Hadi Sorkhi.

Position

children Non-communicable Diseases Research Center Research Assistant.

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