

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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.

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3372 4668

###### Email address

manochehri.saide@yahoo.com

##### 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/پ/ز

## 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

##### Street address

Amir Kola Children Hospital, Babol, Mazandran, Iran.

##### City

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## Person responsible for scientific inquiries

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Mr.Doctor Mousa Ahmadpour  
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## Person responsible for updating data

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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*