

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of planned lighting on weight gain and length of stay of preterm infants

#### Protocol summary

##### Summary

This study is an experimental study to determine the impact of the planned lighting on the weight gain and length of stay in preterm infants admitted to the neonatal intensive care unit in Mofid children's Hospital will be done. Inclusion criteria: respiratory distress syndrome or apnea of prematurity; lack of physical abnormalities and exclusion criteria: jaundice, need for surgery; requiring a long period of continuous lighting for treatment interventions; infants who died before discharge. The study population included all preterm infants 30 to 37 weeks with birth weight of 1500 to 2500 admitted to Mofid children's Hospital. The sample size in this study is 66 preterm infants. From 7 am to 7 pm infants in the intervention group will receive usual light and from 7 pm to 7 Am brightness is reduced by putting dimming cover of light on the head. When intervention group were incubated and did not need respiratory support, in order to avoid disrupting the air flow, the incubator was pulled by cotton cloth. This intervention will maintain until discharge. While at all hours of the day the control group will receive usual light in NICU.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016073129141N1**

Registration date: **2016-09-13, 1395/06/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-13, 1395/06/23

##### Registrant information

###### Name

Elahe Aghaziarati Farahani

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services. School of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5366

##### Email address

ela.farahani@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

investigator

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-11-21, 1395/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of planned lighting on weight gain and length of stay of preterm infants

##### Public title

Effect of planned lighting on weight gain and length of stay of infant

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: 30-37 weeks' gestation; Birth weight between 1500-2500; Apgar score equal or more than 7; neonates suffered from respiratory distress syndrome or apnea of prematurity; Lack of life-threatening problem; lack of physical abnormalities. exclusion criteria:

jaundice, need for surgery; requiring a long period of continuous lighting for treatment interventions; infants who died before discharge.

#### **Age**

To **1 year** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **66**

#### **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**

University of Medical Sciences and Health Services  
Shahid Beheshti

##### **Street address**

next Shahid Ayatollah Taleghani Hospital, Arab street,  
Street Yemen, Shahid Chamran Highway, Tehran

##### **City**

Tehran

##### **Postal code**

1985717443

#### **Approval date**

2016-04-20, 1395/02/01

#### **Ethics committee reference number**

IR.SBMU.RAM.REC.1394.606

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Preterm infant

#### **ICD-10 code**

p07.3

#### **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**

planned lighting

#### **Timepoint**

after intervention

#### **Method of measurement**

profile

## **Secondary outcomes**

### **1**

#### **Description**

weight gain

#### **Timepoint**

Since the infant hospitalization in NICU until discharge

#### **Method of measurement**

Baby Weighing Scale

### **2**

#### **Description**

length of stay

#### **Timepoint**

Since the infant hospitalization in NICU until discharge

#### **Method of measurement**

number of days

## **Intervention groups**

### **1**

#### **Description**

From 7 am to 7 pm infants in the intervention group will receive usual light and from 7 pm to 7 Am brightness is reduced by putting dimming cover of light on the head. When intervention group were incubated and did not need respiratory support, in order to avoid disrupting the air flow, the incubator was pulled by cotton cloth. This intervention will maintain until discharge

#### **Category**

N/A

### **2**

#### **Description**

at all hours of the day the control group will receive usual light in NICU.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Mofid children's Hospital

##### **Full name of responsible person**

Manighe Nourian  
**Street address**  
Mofid Childrens Hospital, Shariati Ave, Tehran, Iran  
**City**  
Tehran

**Email**  
sbnmf@sbmu.ac.ir  
**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
-  
**Full name of responsible person**  
-  
**Street address**  
-  
**City**  
-  
**Grant name**  
-  
**Grant code / Reference number**  
-  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
-  
**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**  
Shahid Beheshti University of Medical Sciences and Health Services, School of Nursing and Midwifery  
**Full name of responsible person**  
Elahe Aghaziarati Farahani  
**Position**  
Master student  
**Other areas of specialty/work**  
**Street address**  
Faculty of Nursing and Midwifery, the intersection of Niyayesh, Vali Asr Street ,Tehran  
**City**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8865 5366  
**Fax**  
+98 88202521

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services, School of Nursing and Midwifery  
**Full name of responsible person**  
Manigheh Nourian  
**Position**  
Science Committee  
**Other areas of specialty/work**  
**Street address**  
Faculty of Nursing and Midwifery, the intersection of Niyayesh, Vali Asr Street ,Tehran  
**City**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8865 5366  
**Fax**  
+98 88202521  
**Email**  
sbnmf@sbmu.ac.i  
**Web page address**  
www.nm.sbmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services, School of Nursing and Midwifery  
**Full name of responsible person**  
Elahe Aghaziarati Farahani  
**Position**  
Master student  
**Other areas of specialty/work**  
**Street address**  
Faculty of Nursing and Midwifery, the intersection of Niyayesh, Vali Asr Street ,Tehran  
**City**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8865 5366  
**Fax**  
+98 88202521  
**Email**  
sbnmf@sbmu.ac.ir  
**Web page address**  
www.nm.sbmu.ac.ir

## 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*