

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### A comparison of the effect of blue light and green light with normal light on the vital signs and level anxiety of patients admitted to CCU

#### Protocol summary

##### Study aim

Comparison of the effect of blue light and green light with normal light on vital signs and anxiety of hospitalized patients in CCU ward of Imam Khomeini Hospital in Esfarayen

##### Design

This study will be a clinical trial on 75 patients admitted to CCU ward of Imam Khomeini Hospital in Esfarayen. These patients were randomly selected from 70-30 years of age. Patients are randomly divided into three groups due to space constraints at three different times.

##### Settings and conduct

Intervention is performed in CCU ward. Spielberger anxiety questionnaire is used for all patients included in the study. The control group for the new white lamp has 10 units in the whole ambient area. Patients are monitored and blood pressure, heart rate, spo2 and respiratory rate are checked and charted every half hour. In the second group, the blue light bulb with 60 Hz voltage and 55 mA current is used. At the end of the third day of hospitalization, the patient completed the anxiety questionnaire. In the third group the green LED lamp and all the cases in the second group are observed in the third group

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 30 and 70 years, consent, no cognitive and cognitive impairment, hospitalization in CCU Exclusion criteria: Having a history of mental illness, suffering from severe asthma, having an eye problem such as color blindness, 39 degree fever, severe hypoxia

##### Intervention groups

Patients admitted to CCU are divided into three groups, the usual light control group and the other two groups use blue and green light.

##### Main outcome variables

Vital signs including blood pressure, respiratory rate, heart rate, temperature, and arterial oxygen saturation percentage 2- Anxiety level of hospitalized patients by

Spielberger questionnaire

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20191129045546N1**

Registration date: **2019-12-12, 1398/09/21**

Registration timing: **prospective**

Last update: **2019-12-12, 1398/09/21**

Update count: **0**

##### Registration date

2019-12-12, 1398/09/21

##### Registrant information

##### Name

Farzaneh Hosseinpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3722 5426

##### Email address

hosseinpourf97@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-04-19, 1399/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

A comparison of the effect of blue light and green light with normal light on the vital signs and level anxiety of patients admitted to CCU

## Public title

"The effect of blue light and green light with normal light on vital signs and anxiety level of patients"

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

1- Age between 30 and 70 years 2- Full patient consent to participate in the research as planned 3. No cognitive and cognitive impairment (coma, hearing loss, blindness, lack of awareness of time, place and person) 4- Being admitted to ccu 5. Ability to recognize colors

### Exclusion criteria:

1- Having a history of mental illness 2- Diseases like severe asthma 3. Having an eye problem such as color blindness 4- Fever above 39 degrees 5. Severe hypoxia and spo2 below 85%

## Age

From **30 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

More than 1 sample in each individual

Number of samples in each individual: **25**

Patients 30-70 years old admitted to CCU ward of Imam Khomeini Hospital in Esfarayen

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, simple sampling is done based on inclusion and exclusion criteria, and then simple random allocation will be assigned to each of the three groups in two intervention groups and one control group respectively. In other words, due to the limitations of the number of part 2, the first, second or control intervention will be randomly selected for implementation. And randomization does not occur in the samples

## 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

Ethics Committee of Sabzevar University of Medical Sciences

##### Street address

No. 12, Isar Street, Sepah Street, Esfarayne

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9661968817

#### Approval date

2019-11-23, 1398/09/02

#### Ethics committee reference number

IR.MEDSAB.REC.1398.066

## Health conditions studied

### 1

#### Description of health condition studied

cardiovascular patients

#### ICD-10 code

قلب

#### ICD-10 code description

قلب

## Primary outcomes

### 1

#### Description

Anxiety of hospitalized patients

#### Timepoint

Measuring the level of anxiety before the intervention and re-measuring it after the intervention

#### Method of measurement

Spiegel Burger Anxiety Inventory

### 2

#### Description

Vital signs

#### Timepoint

From the beginning of the intervention, the patient's vital signs are monitored and charted every half hour and continued until the end of the third day of hospitalization.

#### Method of measurement

Vital signs (heart rate, respiratory rate, blood pressure, arterial saturation rate) are monitored by a monitor and monitored by a thermometer with a thermometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Spilberger anxiety questionnaire is used for patients included in the study. There are 10 numbers on the white LED light bulb. Patients are monitored with the Bliss Mark Monitor and are monitored and charted on a daily basis for ccu blood pressure, heart rate, spo2 and respiratory rate every half hour. The Buliss Mark Oral Thermostat will be used to control the temperature. At the end of the third day of admission to the ccu, the questionnaire is completed again by the patient

#### Category

Treatment - Other

### 2

#### Description

Intervention group 1: In this group, Spiel Berger anxiety questionnaire will be filled out for patients then blue LED light will be used and all 60 Hz blue light bulbs with 55 mA current will be replaced. Patients will be monitored. Blue light will be available for patients from 7am to 12pm, and vital signs will be checked and monitored at half-hour intervals. Vital signs are checked during the time the light is not placed on the patient and at the end of the hospital stay the anxiety questionnaire is filled out.

#### Category

Treatment - Other

### 3

#### Description

Intervention group 2: In this group, Spiel Berger anxiety questionnaire will be filled for patients, then green light LED will be used and all light bulbs with 60 Hz voltage and 55 mA current will be replaced. Patients will be monitored. Green light will be available for patients from 7am to 12pm, and vital signs will be checked and monitored at half-hour intervals. Vital signs are checked during the time the light is not placed on the patient and at the end of the hospital stay the anxiety questionnaire is filled out.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Esfarayne

##### Full name of responsible person

Farzaneh Hossein pour

##### Street address

No. 12 , Isar Street, Sepah Street, Esfarayne

##### City

Esfarayne

##### Province

North Khorasan

##### Postal code

9661968817

##### Phone

+98 58 3722 5426

##### Email

HossinpourF97@medsab.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Fereshte Ghorath

##### Street address

No. 12, Isar Street, Sepah Street, Esfarayne

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##### Province

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##### Phone

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##### Email

HossienpourF97@medsab.ac.ir

#### Grant name

9500000 Rials

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sabzevar University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Farzaneh Hosseinpour

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Nursery

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**Province**

Razavi Khorasan

**Postal code**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

This study will be a clinical trial on 75 patients admitted to ccu ward of Imam Khomeini hospital in Esfaryen. These patients were recruited through random sampling and were included in the study excluding patients between the ages of 70-70 years who needed to be admitted to cardiac care units. Patients are randomly divided into three groups due to space constraints at three different times. For this purpose, the Spielberger Anxiety Inventory is administered to all patients included in the study. For the control group, a 60-Hz white light bulb with a current of 55 mA will be provided with a total of 10 units. Patients are monitored with the Bliss Mark Monitor and are monitored and charted daily on ccu blood pressure, heart rate, spo2 and respiratory rate every half hour. The Buliss Mark Oral Thermostat will be used to control the temperature. At the end of the third day of admission to the ccu, the questionnaire is completed again by the patient. The second group will use the blue LED light bulb and all of the 60 Hz blue light bulbs will be replaced with a 55 mA current. Patients will be monitored. Blue light will be available for patients from 7am to 12pm. The vital signs are checked and controlled every half hour according to the control group. The evening light is also set from 17:00 to 22:00. During the time that the light is not placed on the patient (to avoid fatigue, the rest of the time is considered), vital signs are checked and an anxiety questionnaire is filled at the end of the hospital stay. The third group uses a 60 Hz green LED lamp with a current of 55 mA, and all of the second group uses the third group.

**When the data will become available and for how long**

From the beginning of the intervention

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Keeping patients' personal information confidential

**From where data/document is obtainable**

Sabzevar University of Medical Sciences

**What processes are involved for a request to access data/document**

Through email correspondence and automation

**Comments**