Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

pIntervention 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
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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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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 updating data

Contact
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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 Esfarayen. 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