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# Do eye masks and earplugs help ICU patients feel less pain?

**Submission date**
25/12/2025

**Recruitment status**
No longer recruiting

**Registration date**
31/12/2025

**Overall study status**
Completed

**Last Edited**
31/12/2025

**Condition category**
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

**Plain English summary of protocol**
Background and study aims
This study tested whether simple, inexpensive items, an eye mask and earplugs, could help reduce pain in intensive care unit (ICU) patients who were very drowsy or unconscious and couldn't speak. The goal was to see if blocking light and noise could provide a drug-free way to ease discomfort for these vulnerable patients.

Who can participate?
Participants aged 15-81 years with a reduced level of consciousness.

What does the study involve?
Patients were split into two groups. One group wore the eye masks and earplugs overnight (from 9 PM to 4 AM). The other group received normal ICU care without these items. Researchers measured the patients' pain levels (using a special observation tool) and vital signs like heart rate before, during, and after the night.

What are the possible benefits and risks of participating?
Possible Benefits:
• Participants in the intervention group might experience a reduction in pain and discomfort during the night by being shielded from the bright lights and constant noises of the ICU.
• All participants, regardless of group, continued to receive all standard and necessary medical care from the ICU team.
• The knowledge gained from this study could help improve the comfort and care of future ICU patients.

Possible Risks:
• The intervention is considered very low risk. The eye masks and earplugs are standard medical /sleep aids.
• There was a minimal risk of minor skin irritation from the materials.
• The earplugs or mask could be temporarily removed at any time if needed for essential medical care or if they caused any concern to the patient or nurse.
• There was no risk of missing any necessary medical treatment or monitoring, as all standard ICU procedures continued unchanged.

In summary, the study involved a very safe, non-invasive intervention with the potential benefit of increased comfort, while all standard safety and care protocols remained in place.

Where is the study run from?
Bam University of Medical Sciences, Iran.

When is the study starting and how long is it expected to run for?
June 2023 to October 2024.

Who is funding the study?
Rafsanjan University of Medical Sciences, Iran.

Who is the main contact?
Hadi Khoshab, hadikhoshab@gmail.com

# Contact information

### Type(s)
Scientific, Public, Principal investigator


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# Additional identifiers

# Study information

### Scientific Title
The effect of eye masks and earplugs on pain and physiologic indicators in ICU patients with lowered levels of consciousness

### Study objectives
Primary Objective:
To determine the effect of medical eye masks and earplugs on pain in ICU patients with reduced levels of consciousness.
Secondary Objective:
To determine the effect of medical eye masks and earplugs on physiologic indicators (e.g., blood pressure, heart rate, arterial oxygen saturation, respiration rate, temperature) and the level of consciousness in the same patient population.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 12/10/2022, Ethics Committee of Rafsanjan University of Medical Sciences (Rafsanjan University of Medical Sciences, Rafsanjan, 7646767687, Iran; +91319918754; hamidsiba@gmail.com), ref: IR.RUMS.REC.1398.088

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Blinded (masking used)

## Control
Active

## Assignment
Parallel

## Purpose
Device feasibility, Health services research

## Study type(s)

## Health condition(s) or problem(s) studied
Pain in ICU patients with lowered consciousness, studied using eye masks and earplugs.

## Interventions
Participants were randomly allocated to two groups, intervention and control, using a computer-generated randomization sequence with concealed assignment using sequentially numbered, opaque sealed envelopes administered by an independent researcher after eligibility confirmation.

In summary:
• Generation of Sequence: A computer-generated randomization sequence was used.
• Concealment Method: Allocation was concealed using sequentially numbered, opaque, sealed envelopes.
• Administration: The envelopes were administered by an independent researcher who was not involved in participant enrollment or outcome assessment, ensuring allocation concealment.
This method was employed to ensure robust allocation concealment and minimize selection bias.

Intervention Group:
1. Eye Masks: Light-blocking, disposable foam masks, worn securely to prevent light penetration.
2. Earplugs: Acoustic insert foam earplugs (3M E-A-R Classic; Noise Reduction Rating: 29 dB),

inserted to ensure a proper seal.
3. Protocol: Both devices were applied from 9:00 PM to 4:00 AM (7 hours) during one night. They were removed only for essential care, and not for more than 30 minutes.

Control Group:
Received standard ICU routine care during the same hours, without any structured noise or light reduction measures.

### Intervention Type
Device

### Phase
Phase 0

### Drug/device/biological/vaccine name(s)
Eye Masks: Disposable foam eye masks, Earplugs: 3M™ E-A-R™ Classic Foam Earplugs

### Primary outcome(s)
1. Pain measured using the Critical-Care Pain Observation Tool (CPOT), assessed through behavioral observation of facial expression, body movements, muscle tension, and ventilator compliance/vocalization at 1. 5 minutes before the intervention began (Baseline), 90 minutes after the intervention started, and at the end of the intervention (at 4:00 AM, after ~7 hours)

### Key secondary outcome(s))

### Completion date
30/10/2024

## Eligibility

### Key inclusion criteria
1. Age 15-81 years
2. Reduced consciousness level (FOUR score of 8-12)
3. Inability to communicate verbally or report pain
4. No visual or hearing impairments
5. No administration of pain medication for 4 hours prior to intervention
6. Admission to the ICU for at least 24 hours

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
15 years

### Upper age limit
81 years

**Sex**
All

**Total final enrolment**
50

**Key exclusion criteria**
1. Requiring cardiopulmonary resuscitation
2. Absence of legal guardian consent
3. Need for neuromuscular blocking drugs
4. Death, brain death, or discharge from ICU
5. Change in the level of consciousness
6. Need to remove the eye mask and earplugs for more than 30 minutes during the intervention

**Date of first enrolment**
01/06/2023

**Date of final enrolment**
20/07/2024

# Locations

**Countries of recruitment**
Iran

# Sponsor information

**Organisation**
Bam University of Medical Sciences

**ROR**
https://ror.org/02mm76478

# Funder(s)

**Funder type**

**Funder Name**
Rafsanjan University of Medical Sciences

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
Iran

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Data sharing statement to be made available at a later date