

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

To determine the effect of Nursing Measures on patients' sleep quality who are hospitalized in the CCU Heart ward of Ekbatan Hospital in Hamadan city, 1391".

Protocol summary

Summary

Main Goals: To determine the effect of Nursing Measures on patients' sleep quality who are hospitalized in the CCU Heart ward of Ekbatan Hospital in Hamadan city. To design the study: calculated one Population to study: all hospitalized patients in CCU Wards of Ekbatan Hospital
Criteria to enter the Study: • Hospitalized in CCU • No sign of sleep disorder before admission • Having alertness & Orientation Criteria to exit the Study: • Discharging before day 3 • Losing consciousness • Clinical Deterioration of the patient
Sample Size: 166
Patients Measures taken into study: • Assessing the sleep quality of Control Group • Educating Nursing Measures developed for a proper Sleep e.g., Environment Factor Control, providing Nursing and Medical Interventions at the right time, Pain and Stress alleviation, not using any Diuretics before sleeping time, assessing the Sleep Quality of Control Group after receiving Nursing Measures. Intervention time: The Sleep Quality of Control Group has to be checked on the third morning upon admission. After reaching the samples to the desired level, the required changes in the ward and educating nurses are proceeded during 10 days. Later, the Sleep Quality of group three hospitalized is checked through questionnaires. It is noticed that 10 minutes should be assigned to fill the questionnaires. Study Outcome: • Sleep quality of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091010803N1**
Registration date: **2012-11-06, 1391/08/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-06, 1391/08/16

Registrant information

Name

Mahnaz Moghadari Koosha

Name of organization / entity

Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To determine the effect of Nursing Measures on patients' sleep quality who are hospitalized in the CCU Heart ward of Ekbatan Hospital in Hamadan city, 1391".

Public title

Evaluation the effect of Nursing Measures on patients'

sleep quality who are hospitalized in the CCU ward

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Hospitalized in CCU; No sign of sleep disorder before admission; Having alertness & Orientation
Exclusion Criteria: Discharging before day 3; Losing consciousness; Clinical Deterioration of the patient

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **166**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double 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 the Hamadan University of Medical Sciences

Street address

Shahid fahmide avenue, Hamadan University of Medical Sciences

City

Hamadan

Postal code

6517838695

Approval date

2012-08-13, 1391/05/23

Ethics committee reference number

1838/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

heart disease

ICD-10 code

Y84.0, Z50

ICD-10 code description

Cardiac catheterization, Cardiac rehabilitation, Cardiac arrest with successful resuscitation, Other cardiac arrhythmias, Paroxysmal tachycardia, Atrial fibrillation and flutter, Acute myocardial infarction, Subsequent myocardial infarction, Old myocardial inf

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention, 2week after intervention.

Method of measurement

SMHSQ questionnaire

Secondary outcomes

1

Description

Nursing measures

Timepoint

before intervention, after intervention

Method of measurement

questionnaire made by scholar

Intervention groups

1

Description

Control Group receives the routine Nursing Care in CCU Ward. It means that no changes will be applied in the ward and no training will be given to staff as well.

Category

Other

2

Description

After sampling the Control Group, Nursing measures are trained to nurses in 10 days, including environment factor Control like sound reduction by speaking softly, using silent Shoes, replacing damaged chairs, preparing medications in the treatment room, applying phones with flashes instead of rings, changing worn trolleys, modulating lights and temperature. Furthermore, other measures are; providing Nursing and Medical measures at the right time, relieving pain, averting stress and using no diuretics close to sleep time. Finally, after implementing Nursing Measures, in the morning of the third day of admission, the quality of Sleep of the participated/case Group will be measured via SMHSQ.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Hospital in Hamadan city

Full name of responsible person

Mahnaz Moghadari Koosha

Street address

Taleghani avenue, Jihad field

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Ahmad Tavilani

Street address

Shahid Fahmide avenue

City

Hamadan

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 and Technology, Hamadan
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

Research Center for Health Sciences, Department of
Epidemiology & Biostatistics

Full name of responsible person

Dr Javad Faradmali

Position

MD, PhD, Assistant Professor of Stats

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Internal Medicine and Surgery, Nursing
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Full name of responsible person

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Position

Phd

Other areas of specialty/work

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Person responsible for updating data

Contact

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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