

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

#### Protocol summary

##### Summary

The current study examines the effects of multifactorial intervention to improve sleep in patients admitted to coronary care unit. This quasi-experimental study was conducted in 1390 in a hospital doctor Shariati in Iran. The study sample consisted of 60 patients were admitted to the coronary care unit that the following criteria were: Being hospitalized for at least three nights, be aware of time and place and no need for cardiopulmonary resuscitation, no medical history of neurological and psychiatric disorders, not receiving medications affecting sleep, like amphetamines, opiates at night, and if the patient is discharged in less than three days, need for CPR during the study and receiving disturbing sleep medications such as drugs, diuretics, amphetamines, opiates at night, samples were excluded. Specimens available for study were selected and control group was tested in the first and then experimental group. Nursing Based Multifactorial intervention was doing in the first three night's admission in experimental group and includes: reducing the environmental factors disturb sleep, changing care practices for sleep was not interrupted and in the control group took part in the routine caring. Sleep quality was measured by Pittsburgh questionnaire. With the analyzing of data in both groups, significant improvement in the experimental group is expected to sleep.

#### General information

##### Acronym

The effect of Nursing interventions on sleep of hospitalized patients

##### IRCT registration information

IRCT registration number: **IRCT201109171599N12**  
Registration date: **2011-12-11, 1390/09/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-12-11, 1390/09/20

##### Registrant information

###### Name

Mitra Zolfaghari

###### Name of organization / entity

Tehran University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences, Medical, Nursing and Health Care Research Center

##### Expected recruitment start date

2011-09-11, 1390/06/20

##### Expected recruitment end date

2012-01-10, 1390/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

##### Public title

The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

## Purpose

Supportive

## Inclusion/Exclusion criteria

The inclusion criteria of the study; Patients are admitted to the coronary care unit for at least three days; be aware of time and place; and no need for cardiopulmonary resuscitation; no medical history of neurological and psychiatric disorders; not receiving medications affecting sleep, like amphetamines, opiates and sedatives at night. Exclusion criteria of the study: Patients being discharged in less than three days; to receive sedating medications and general anesthesia; need for CPR during the study; neurological and psychiatric diseases in the patient's medical history; receiving medications affecting sleep medications such as diuretics, hypnotics, and amphetamines, opiates at night; and the patient did not wish to continue study.

## Age

From 20 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

To reduce the effects of confounding variables, research is conducted in a single CCU Dr.Shariati hospital

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

CENTER OF NURSING AND MIDWIFERY  
RESEARCH, Tehran University of Medical Sciences

##### Street address

TEHRAN UNIVERSITY OF MEDICAL SCEINCES FACUITY  
OF NURSING AND MIDWIFERY, SQUARE OF THOHID,  
TEHRAN

##### City

TEHRAN

##### Postal code

ندارد

## Approval date

2010-09-23, 1389/07/01

## Ethics committee reference number

1468/130/90/3

## Health conditions studied

### 1

#### Description of health condition studied

Sleep

#### ICD-10 code

G47.8

#### ICD-10 code description

Other sleep disorders

## Primary outcomes

### 1

#### Description

Sleep quality

#### Timepoint

On the first day and three days after admission

#### Method of measurement

Pittsburgh Questionnaire

## Secondary outcomes

### 1

#### Description

Sleep quantity

#### Timepoint

every day for three days

#### Method of measurement

Researcher made questionnaire

## Intervention groups

### 1

#### Description

Data quality and quantity of sleep during hospitalization was measured using a questionnaire in experimental group then the intervention is conducted, including: A) Adjusting environmental factors which include: reducing the light and sound and Setting the temperature at night, B) educating nurses about the importance of sleep and sleep in patients with heart disease and insomnia factors, C) changing routine care procedures for patients to improve sleep. Then, the patient's sleep quality is measured again by using the same questionnaire three days after admission.

#### Category

Behavior

### 2

#### Description

Data quality and quantity of sleep during hospitalization was measured using Pittsburgh questionnaire in control

group and then qualitative and quantitative characteristics of the patients with the sleep questionnaire is measured again three days after admission while routine care during in these three days for the control group was done.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Doctor Shariati Hospital

**Full name of responsible person**

Pouya farokh nezhad afshar

**Street address**

Tehran- kargar street

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences

**Full name of responsible person**

Mitra Zolfaghari

**Street address**

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences, FACULTY OF NURSING AND MIDWIFERY, EAST NOSRAT ST, SQUARE OF THOHID, THERAN, IRAN

**City**

Tehran

**Grant name**

Phd

**Grant code / Reference number**

در حال بررسی

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

Yes

**Title of funding source**

Nursing and Midwifery Care Research Center, Tehran 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

**Full name of responsible person**

Mitra Zolfaghari

**Position**

Instructor

**Other areas of specialty/work****Street address**

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Non

**Person responsible for updating data****Contact****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