Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

"The effect of acupressure with valerian Oil2/5% on Quality and Quantity of sleep of patients with Acute coronary Syndrome (ACS)"

Protocol summary

Summary

Objectives: This study aimed to evaluate the effect of acupressure with valerian oil 2/5% on the quantity and quality of sleep in patients with coronary syndrome hospitalized in CCU Design: this study, a clinical trial is a single-blind, placebo-controlled groups. On 90 patients with acute coronary syndrome in CCU. The samples will be selected of the population, and after obtaining informed consent, were randomly divided into three groups of . In all three groups to assess the quality and quantity of sleep, will be used the SMHSQ questionnaire and sleep log. Setting and conduct: In all three groups before intervention SMHSQ questionnaire as the measurement basis, will be completed and the acupoint massage) will do from second night for three consecutive nights (between the hours of 7-10pm) for patients both groups (Acupressure and Valerian oil Acupressure. In the acupressure group patients and control patients were referred to instead of valerian oil, almond oil will be used As a control group, acupoint massage (5/1 -1 cm distance from the actual point) will get technique and the same time. Participants include major eligibility criteria: a condition of entry into the study included age over 18 years; orientation to time ond place; No need for surgery; EF Over 40 percent; of knowledge and timedrug addiction; and if patients Receiving opioid analgesics for 5 to 6 hours before bedtime; allergic to flowers and plants; accustomed to using any drug or procedure affecting sleep, use of inotropes drugs, or leg amputation, scar in acupoint, Creates acute problems during the hospitalization and unwillingness to cooperate in research continue will to be excluded. Intervention: The interventions include effective for sleep acupoint massage, so that in acupressure with valerian's group effective for sleep acupoint massage will be with 2 drops of valerian oil 2/5% and in acupressure group the acupoint massage will be use with same time and technique without Valerian oil. acupoint massage do for each sample every night for 18 minutes (2 minutes, 5 seconds for every point a massage and a second rest) by a researcher who is trained. Selected areas are of wrist Shenmen(HT7), (the carpal bones pisiform), ear Shenmen, Yungchuan (k11)-Yin Tang(EX), Feng chi(GV20) in the forehead between the eyebrows and behind (in total 9 points massage is given). Sleep Log and SMHSQ Questionnaire, 7 to 8 hours per day in the morning by someone who is not aware of how to allocate samples in groups, will be completed. The main outcome measure variables: the quality and quantity of sleep

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302277494N3**
Registration date: **2013-08-11, 1392/05/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Science

Expected recruitment start date
2013-03-07, 1391/12/17
Expected recruitment end date
2013-06-07, 1392/03/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"The effect of acupressure with valerian Oil2/5% on Quality and Quantity of sleep of patients with Acute coronary Syndrome (ACS)"

Public title
"The effect of acupressure with valerian Oil 2/5% on Quality and Quantity of sleep of patients with Acute coronary Syndrome (ACS)"
Purpose
Supportive
Inclusion/Exclusion criteria
The main inclusion criteria is at least eighteen years of age; being aware of the time and place of not surgery; EF is above 40%. The main exclusion criteria in this study received the opioid drug five or six hours of sleep the night before; despite hearing and vision impairments (such as not being able to communicate with the investigator if); have addiction to drug; have an allergy to plants and flowersand; habit to use of any matter or procedure affecting the sleep; using inotropes drugs; leg amputation or ulcer at the site of acupoints; acute problems at admission and continuing to investigate the individual does not cooperate.
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Moalem street, Moalem square
City
Sari
Postal code
4816715793
Approval date
2013-03-06, 1391/12/16
Ethics committee reference number
282-91

Health conditions studied

1

Description of health condition studied
Sleep
ICD-10 code
F51.2
ICD-10 code description
Nonorganic disorder of the sleep-wake schedule

Primary outcomes

1

Description
Quality
Timepoint
Before the study -The first to the fourth day of hospitalization
Method of measurement
SMHSQ

Secondary outcomes

1

Description
Quantity of sleep
Timepoint
Baseline and every day until the fourth day.
Method of measurement
Sleep Log

Intervention groups

1

Description
Intervention in first group(Valerian acupressure):Intervention in Acupressure with valerian

oil's group such manner that this patient will received acupoint massage Second night in hospitalization, from the top of the head Respectively in Feng Chi(GB20) behind the head, Yin Tang in forehead, Ear Shen men, wrist Shen men(HT7) and Yungchuan at the sole bilaterally with 3 to 4 kilogram pressure two minute for every acupoint (five second massage and one second relax) A revolving of two seconds away with, A total of eighteen minutes for nine points with Valerian oil2/5% between 7 to 10 PM for three consecutive nights. Valerian oil is extracted of valerian root. In this study, valerian oil 2/5% is prepared from the massage center of Iran under the supervision of professors is reached to the desired concentration with almond base oil

Category

Other

2

Description

Intervention in third group(control): The control group every night between 7 to 10 PM will received shame acupoint massage(1-1/5 Centimeter from true acupoint) in Respectively in Feng Chi(GB20) behind the head, Yin Tang in forehead, Ear Shen men, wrist Shen men(HT7) and Yungchuan at the sole bilaterally with 3 to 4 kilogram pressure two minute for every acupoint (five second massage and one second relax) A revolving of two seconds away with, A total of eighteen minutes for nine points with Neutral Almond oil(available in drugstore) between 7 to 10 PM for three consecutive nights.

Category

Other

3

Description

Intervention in second group (acupressure): Acupressure's group will received acupoint massage from Second night in hospitalization, the top of the head Respectively in Feng Chi(GB20) behind the head, Yin Tang in forehead, Ear Shen men, wrist Shen men(HT7) and Yungchuan at the sole bilaterally with 3 to 4 kilogram pressure two minute for every acupoint (five second massage and one second relax) A revolving of two seconds away with, A total of eighteen minutes for nine points with Neutral almond oil(available in drugstore) between 7 to 10 PM for three consecutive nights.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital

Full name of responsible person

Somayeh Rezaie

Street address

Shahid Hasheminejad Alley, Forodgah St, Behshar

City

Behshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Dr. Ahmahali Enayati

Street address

Vice chancellor for research of Mazandaran University of Medical Science, Moalem street, Moalem square

City

Sari

Grant name

در حال بررسی

Grant code / Reference number

Being investigated

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Science

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

Mazandaran University of Medical Science

Full name of responsible person

Dr Mohammad Ali Heydari Gorgi

Position

Phd- faculty

Other areas of specialty/work

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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