Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Acupressure effect on sleep quality in patients with chronic heart failure

Protocol summary

Summary
The study will conduct to investigation of acupressure effectiveness on sleep quality in patients with chronic heart failure. In this controlled clinical trail, 60 chronic heart failure patients will select from 22 bahman hospital via convenience sampling, then the subjects randomly allocate to three groups (true acupoint group, pseudo acupoint group and control group). EF has more than 20 and less than 40، absence of any lesion on the shenmen point، no history of acupressure and minimum 40 and maximum 65 years are necessary for including to the study. Unwillingness to continue participation in the study for any reason, patient was unavailable for any reason (death, discharge), drugs for 5 to 6 hours before bedtime will lead to withdrawal from the study sample. Subjects in true acupoint group will receive acupressure in hand shenmen points for three nights, placebo acupoint group will experience massage in pseudo points with about 1-1.5 cm distance near to the true points and will not do any intervention in control group. Intervention will be take place in heart unit by a trained practitioner (Project Officer). Pre and post test for measurement of sleep with Sleep Quality Index SMHSQ.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2014103019761N1**
Registration date: **2015-01-10, 1393/10/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-01-10, 1393/10/20

Registrant information

Name
Reza Bordbar

Name of organization / entity
Sabzevar University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Sabzevar University of Medical Sciences

Expected recruitment start date
2014-08-04, 1393/05/13

Expected recruitment end date
2015-01-03, 1393/10/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Acupressure effect on sleep quality in patients with chronic heart failure

Public title
Acupressure effect on sleep quality in patients with chronic heart failure

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:Patients with systolic heart failure and left ventricular ejection fraction (Ef) is greater than 20 and less than 40%؛ In the absence of any injury at the shenmen point؛ No history of acupressure ؛ Having awareness؛ listening and speaking abilities at an acceptable level to accountability؛ Minimum 40 and maximum 65 years Exclusion criteria:Unwillingness to continue participation in the study؛ Out of reach of the

patient(Death،discharge)؛ Get opium for 5 to 6 hours before bedtime؛ Use sedative drugs

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
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 Sabzevar University of Medical Sciences

Street address
Vice chancellor for research of Sabzevar University of Medical Science, 5th km of Sabzevar to Tehran Road, Sabzevar

City
Sabzevar

Postal code
9613873136

Approval date
2014-08-04, 1393/05/13

Ethics committee reference number
(medsab.Rec.93.30)

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
sleep quality

Timepoint
Before the intervention- First to fourth day of hospitalization

Method of measurement
SMHSQ Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The third group (control group), a group that receives the usual routine procedures.These sleep quality with SMHSQ questionnaire at the time of admission (for the study of sleep in the house), on the morning of the second, third, fourth and fifth admitted between the hours of 7 to 8 am will be reviewed by the project partners.

Category
Other

2

Description
The second group intervention (The false point): these patients, the second night in hospital the point with 1-1.5 cm distance of shenmen point of bilaterally with a pressure of about 3 to 4 kg massage for five minutes receive (5 seconds massage and one second rest) for a period of two revolutions per second with a thumb rest for three consecutive nights between 7pm to 10pm. These sleep quality with SMHSQ questionnaire at the time of admission (for the study of sleep in the house), on the morning of the second, third, fourth and fifth admitted between the hours of 7 to 8 am will be reviewed by the project partners.

Category
Other

3

Description
Intervention in first group(acupressure): these patients, the second night in hospital shenmen point bilaterally with a pressure of about 3 to 4 kg massage for five minutes receive (5 seconds massage and one second rest) for a period of two revolutions per second with a thumb rest for three consecutive nights between 7pm to 10pm. These sleep quality with SMHSQ questionnaire at the time of admission (for the study of sleep in the house), on the morning of the second, third, fourth and fifth admitted between the hours of 7 to 8 am will be reviewed by the project partners.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman Hospital
Full name of responsible person
Reza Bordbar
Street address
22 Bahman Hospital، Emam Khomeini Street، Neyshaboor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Science
Full name of responsible person
Dr. Mohammad Mohammadzade
Street address
Vice chancellor for research of Sabzevar University of Medical Science, 5th km of Sabzevar to Tehran Road, Sabzevar
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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

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Person responsible for scientific inquiries

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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