

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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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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

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Neyshaboor

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

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Full name of responsible person

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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****Contact****Name of organization / entity**

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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