

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of foot reflexotherapy on physiological Indexes and weaning time after open heart surgery in Baqiyattallah university of medical sciences hospitals

Protocol summary

Summary

The purpose of this study is to investigate the effect of foot reflexology massage on the physiological indexes and weaning time in patients undergoing open heart surgery. This clinical trial will be conducted in three groups. 90 patients who are undergoing open heart surgery who have our study inclusion criteria will be randomly allocated into three groups: control, experimental and placebo groups. After adequate explanations, written informed consent was obtained from patients. After transferring patients from to the intensive care unit, and the first hour time the foot reflexology massage was applied in experimental group patients in both legs in reflex points of heart and lung for 20 minutes. Vital signs were recorded in different times consist of ICU entrance, immediately after the first hour time, immediately and 10 minutes after intervention and during extubation and one hour after extubation. The time of the entrance patient until extubation will be recorded. There control group will receive the routine care. In placebo group after past one hour receive the massage in the heels of both legs for 20 minutes. Weaning time and vital signs are recorded and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401046778N3**
Registration date: **2014-04-24, 1393/02/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-24, 1393/02/04

Registrant information

Name

Seyed Tayeb Moradian Vafaei

Name of organization / entity

School of nursing and midwifery, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Nursing faculty, Baghyattallah University of Medical Sciences

Expected recruitment start date

2014-02-28, 1392/12/09

Expected recruitment end date

2014-05-30, 1393/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexotherapy on physiological Indexes and weaning time after open heart surgery in Baqiyattallah university of medical sciences hospitals

Public title

The Effect of Foot Reflexotherapy on Physiological Indexes and Weaning Time

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with non-emergency cardiac surgery; age greater than 18 and less than 75 years; has a heart rate greater than 60 beats per minute; systolic blood pressure greater than 90 mm Hg; healthy legs
Exclusion criteria were: hemodynamic instability; delayed weaning process based on the physician's order; return to the operating room; dependence to the intra aortic balloon pump

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Science

Street address

Molla Sadra Ave, Vanak Square, Tehran

City

Tehran

Postal code

Approval date

2014-01-05, 1392/10/15

Ethics committee reference number

Meeting No. 34

Health conditions studied

1

Description of health condition studied

cardiac surgery

ICD-10 code

j95.1

ICD-10 code description

Acute pulmonary insufficiency following thoracic surgery

Primary outcomes

1

Description

Weaning Time

Timepoint

Since entering until extubation

Method of measurement

Using the Clock

2

Description

Physiological Indexes

Timepoint

Log since the first time at the reception immediately following the intervention, ten minutes after the intervention, during extubation, and an hour later

Method of measurement

Using Patient Monitoring

Secondary outcomes

1

Description

Reduce anxiety

Timepoint

Since entrance patient, the first hour, immediately and 10 minutes after massage and extubation and one hour after extubation

Method of measurement

FAS criteria

Intervention groups

1

Description

intervention groups , Foot reflexology in this case,The first step should be holding foot for a minute. Secondly, for each foot perform foot spread for a minute. In the third stage, the four fingers of both hands on the dorsal surface of the foot (the left foot, then right foot) has been given the thumbs on the hands (the Ball every foot reflexology areas of the heart and lungs are in this area) rotating basis 7-10 minutes and with gentle pressure massage will. And the final step will take a minute Top sliding. Overall, both legs will massage for 20 minutes.

Category

Other

2

Description

Placebo treatment group after the first hour, the soles of both feet will touch the surface. A total duration of 20 minutes for both legs (each leg separately, 10 minutes) will be.

Category

Other

3**Description**

The control group received no intervention and usual care patients will be monitored.

Category

Other

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

jamaran Heart Hospital

Full name of responsible person**Street address**

Jamaran Heart hospital, Jamaran st, Niavaran St,
Tehran

City

Tehran

2**Recruitment center****Name of recruitment center**

Hospital Baqiyatallah

Full name of responsible person**Street address****City**

Tehran

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

School of Nursing - University of Medical Sciences ...
(Aj)

Full name of responsible person

doctor Abbas Ebadi

Street address

Tehran, Sadra St., St. Sheikh Bahai University of
Medical Sciences ... (Aj)

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

School of Nursing - University of Medical Sciences ... (Aj)

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**

Nursing Faculty, Baghiyatallah university of medical
sciences

Full name of responsible person

Seyed Tayeb Moradian

Position

Faculty member

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

Tehran, Sadra St., St. Sheikh Bahai University of
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing faculty, Baghiyatallah University of medical
sciences

Full name of responsible person

Dr Abbas Ebbadi

Position

The faculty Member

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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