Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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,immediatly and10 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)

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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; dependance 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, Baghiyyatallah university of medical sciences
Full name of responsible person
Seyed Tayeb Moradian
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Faculty member
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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
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Baghiyatallah University of medical sciences, Sheykh Bahaei street, Tehra
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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