

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effects of Foot Reflexology on the Incidence of Delirium, Sleep Disorder and Pain in Patients after Open Heart Surgery in Baghiatollah and Jamaran Hospital in 2017 and 2018

Protocol summary

Study aim

The Effect of Foot Reflexology Massage on the Incidence of Delirium, Pain and Sleep Disorders in Patients after Open Heart Surgery

Design

This Study is a Clinical Trial Study with a Control Group with Parallel Groups

Settings and conduct

Includes all patients admitted to Baqiyatallah and Jamaran hospitals for open heart surgery and transferred to intensive care unit after open heart surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: open heart surgery for first time; non emergency open heart surgery; healthy foot. Exclusion criteria: opium addiction; severe hearing impairment; existential psychological problems.

Intervention groups

In the experimental group after open heart surgery and transfer to the intensive care unit and 2 hours after the patient's removal from mechanical ventilation, the first session of massage therapy and the second session will be performed the next day after surgery. The Questionnaires were completed on the first and second morning after surgery. In the control group the questionnaires were completed without the intervention on the first and second days after surgery.

Main outcome variables

Delirium, sleep disorder, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044268N1**

Registration date: **2020-01-23, 1398/11/03**

Registration timing: **retrospective**

Last update: **2020-01-23, 1398/11/03**

Update count: **0**

Registration date

2020-01-23, 1398/11/03

Registrant information

Name

Ahmad Fazlolah

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 3334 5665

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

2018-10-07, 1397/07/15

Actual recruitment end date

2019-05-21, 1398/02/31

Trial completion date

2019-06-21, 1398/03/31

Scientific title

The Effects of Foot Reflexology on the Incidence of Delirium, Sleep Disorder and Pain in Patients after Open Heart Surgery in Baghiatollah and Jamaran Hospital in 2017 and 2018

Public title

Effects of Foot Reflexology on the Incidence of Delirium, Sleep Disorder and Pain in Patients after Open Heart

Surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Open heart Surgery for First Time Non Emergency Open Heart Surgery Healthy Foot
Exclusion criteria:
Opium Addiction Severe Hearing Impairment. Existential Psychological Problems.

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were assigned to Experimental and Control Groups using four blocks Method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatollah University of Medical Science

Street address

Baqiyatollah University of Medical Sciences, Sheikh Bahaee St, Molla Sadra St, Vanak Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2018-08-04, 1397/05/13

Ethics committee reference number

IR.BMSU.REC.1397.023

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2

Description of health condition studied

Sleep Disorder

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

3

Description of health condition studied

Pain

ICD-10 code

F45.4

ICD-10 code description

Pain disorders related to psychological factors

Primary outcomes

1

Description

Delirium

Timepoint

At 14, 19 and 6 in the morning after the first intervention session and at 14, 19 and 6 in the morning after the second intervention.

Method of measurement

(Delirium Observation Scale (DOS

2

Description

Sleep Disorder

Timepoint

At 14:00 in the Mid day after the first intervention session and at 14:00 in the Mid day after the second intervention session.

Method of measurement

Richards Campbell Sleep Questionnaire

3

Description

Pain

Timepoint

In the Intervention group before the intervention and immediately after the intervention and the third time, two hours after the intervention, which will be completed 6 times in two days according to the two intervention

sessions and in the control group, two times in the First day and Second day After Extubation .

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Blood Pressure

Timepoint

After surgery, immediately after entering to ICU OH, before each intervention session and after intervention and two hours after intervention and in the control group, in addition to entering the ward, once ,first day after The operation was evaluated and second time was in the second morning after surgery.

Method of measurement

Patients Blood Pressure Monitoring

2

Description

Heart Rate

Timepoint

After surgery, immediately after entering to ICU OH, before each intervention session and after intervention and two hours after intervention and in the control group, in addition to entering the ward, once ,first day after The operation was evaluated and second time was in the second morning after surgery.

Method of measurement

Patient Monitoring Device

3

Description

Respiratory Rate

Timepoint

Immediately after the patient's admission to the ICU OH department

Method of measurement

Patient Monitoring Device

4

Description

Saturation of Oxygen in Blood

Timepoint

Immediately after the patient's admission to the ICU OH department

Method of measurement

Patient Monitoring Device

5

Description

Patients temperature

Timepoint

Immediately after the patient's admission to the ICU OH department

Method of measurement

Thermometer

Intervention groups

1

Description

Intervention group: Patients in the intervention group were enrolled after open heart surgery after entering ICU OH ward for primary vital signs and demographic characteristics. After the initial symptoms persisted and arterial blood gas tests resolved, the patient's endotracheal tube was removed according to the patient's signs and physician's order. About 10 minutes after the endotracheal tube was removed, the first session of reflexology massage was performed for 20 minutes. The second intervention was performed in the morning after surgery.

Category

Treatment - Other

2

Description

Control group: The control group was enrolled after open heart surgery after entering ICU OH department for primary vital signs and demographic characteristics. In these patients, normal and routine care for patients was performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jamaran Heart Hospital

Full name of responsible person

Dr Mohammad Hassan Naseri

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Jamaran Heart Hospital, Jamaran St, Niavaran St, Tehran

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2

Recruitment center

Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Dr Hossein Samadi Nia
Street address
Mulla Sadra Street in Vanak, Tehran, Iran.
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Baqiatollahhos@Bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Ali Reza Jalali
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Baqiatollah Hospital, Mulla Sadra St, Vanak Sq,
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Tayeb Moradian
Position
Faculty Member
Latest degree
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Other areas of specialty/work
Medical Education
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main variables and dependent variables, can be shared.

When the data will become available and for how long

Start accessing 8 months after printing results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In case of research in similar fields and with the discretion of the respected professor

From where data/document is obtainable

Email a.fazlolah@gmail.com

What processes are involved for a request to access data/document

Upon email access to one week of documentation or files will be available

Comments