# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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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 Bahaei St, Molla Sadra St, Vanak Square, Tehran, Iran

**City**

Tehran

**Province**

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**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 Secound day After Extubation .

**Method of measurement**

Visual Analoge 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 ŝighns 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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### 2

**Recruitment center**

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Dr Hossein Samadi Nia
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## Sponsors / Funding sources

### 1

**Sponsor**
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**Full name of responsible person**
Dr Ali Reza Jalali
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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**
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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**