

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of foot reflexology massage on the duration of maximal consciousness and weaning of Ventilator in patients with brain tumor after craniotomy surgery

Protocol summary

Study aim

Determining the effect of foot reflexology massage on the duration of maximal consciousness and weaning of Ventilator in patients with brain tumor after craniotomy surgery

Design

In this randomized clinical trial, patients will be randomly assigned to two groups of 30 people.

Settings and conduct

This study will be performed in the intensive care unit of Shahid Beheshti Hospital in Kashan. 60 patients are randomly divided into two groups of intervention (foot reflexology) and control. Outcomes are assessed 1 to 7 days after surgery. Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having the consent to participate in the study, Age 18-65 years, The patient's level of consciousness should be between 5 and 7 according to the Glasgow Coma Criterion, Patients underwent craniotomy surgery and hospitalization in the intensive care unit, The patient is connected to a ventilator. Exclusion criteria: Patients who need a long-term intubation at the discretion of a neurosurgeon

Intervention groups

In the intervention group, foot reflexology will be performed for 15 minutes for each foot and twice a day for a week. The control group will not receive any intervention for a week and will receive routine care such as medication.

Main outcome variables

Achieve consciousness and weaning of Ventilator

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111210008348N47**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Neda Mirbagher

Name of organization / entity

Kashan University of Medical Science

Country

Iran (Islamic Republic of)

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+98 36 1555 0021

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mirbagher_n@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on the duration of maximal consciousness and weaning of Ventilator in

patients with brain tumor after craniotomy surgery

Public title

The effect of foot reflexology massage on the duration of maximal consciousness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the consent to participate in the study Age 18-65 years The patient's level of consciousness should be between 5 and 7 according to the Glasgow Coma Criterion Patients underwent craniotomy surgery and hospitalization in the intensive care unit. The patient is connected to a ventilator.

Exclusion criteria:

Patients who need a long-term intubation at the discretion of a neurosurgeon

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using a randomizer tool (<https://www.randomizer.org>).

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

Ethics committee of Kashan University of Medical Sciences

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.026

Health conditions studied

1

Description of health condition studied

Reflexology

ICD-10 code

Z50

ICD-10 code description

Care involving use of rehabilitation procedures

Primary outcomes

1

Description

Achieve consciousness

Timepoint

Before the intervention and the first to seventh days after surgery

Method of measurement

The Glasgow Coma Scale

Secondary outcomes

1

Description

Weaning of ventilator

Timepoint

Before the intervention and the first to seventh days after surgery

Method of measurement

Researcher checklist

Intervention groups

1

Description

Intervention group: In addition to routine care (medication), foot reflexology therapy in three stages including preparation, warm-up and stimulation and massage techniques will be performed for 30 minutes (15 minutes for each foot) and twice a day, morning and evening for a week by the researcher.

Category

Treatment - Other

2

Description

Control group: Only routine care including medication will be performed for patients by health personnel. No intervention will be performed for them during the research.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unit of Kashan Shahid Beheshti Hospital

Full name of responsible person

Neda Mirbagher

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

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Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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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

Kashan University of Medical Sciences

Proportion provided by this source

100

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

Kashan University of Medical Sciences

Full name of responsible person

Neda Mirbagher

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Master's degree student in nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Kashan, Iran**City**

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Province

Isfahan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable