

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effects of light pressure stroking massage with olive oil placebo on pain severity and dose of received analgesic in patients with upper or lower limbs trauma

Protocol summary

Study aim

Comparison the effect of light pressure stroking massage with olive oil and placebo on pain severity and dose of received analgesic in patients with upper or lower limbs trauma

Design

In this research, 60 eligible patients referring to Tehran Beasat Hospital will be selected with consecutive sampling method. Patients will be randomly allocated to two equal groups of massage with olive oil and placebo using sealed envelopes.

Settings and conduct

This study will be conducted on Tehran Beasat Hospital. Patients, outcomes assessor, and care provider will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range of 15 to 50 years; being fully conscious and having the ability to read and write in Persian; presence of one limbs trauma which passed a maximum of six hours and at least one hour of its initiation; experience of regional and moderate pain on the trauma site based on the visual analog scale (obtaining a score of four to seven) during the admission time. Exclusion criteria: any infections, bone fractures, internal and external bleedings, dislocations, amputations, and nerve damages on the affected limb during the admission time; having confirmed deep vein thrombosis; taking anti-coagulants, analgesics, tranquilizers or sedatives, and any topical herbal extracts in the past three months; absence of cast or splint on the trauma site; having history of diabetes, cardiovascular diseases, musculoskeletal disorders, gastrointestinal bleedings, allergic reactions to any herbal extracts, and addiction to drugs or alcohol.

Intervention groups

Trauma site will be massaged through light pressure stroking method with olive oil in the intervention group

and with placebo in the control group twice a day for nine consecutive days.

Main outcome variables

Pain severity and dose of received analgesic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130803014251N8**

Registration date: **2019-01-21, 1397/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-21, 1397/11/01**

Update count: **0**

Registration date

2019-01-21, 1397/11/01

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 2622 5292

Email address

nasiri.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of light pressure stroking massage with olive oil placebo on pain severity and dose of received analgesic in patients with upper or lower limbs trauma

Public title

effects of massage on pain in traumatic patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 15 to 50 years Being fully conscious and having the ability to read and write in Persian Presence of one limbs trauma which passed a maximum of six hours and at least one hour of its initiation Experience of regional and moderate pain on the trauma site based on visual analog scale (obtaining score of 4 to 7) during the admission time confirmation of appropriate perfusion on the trauma site by a physician

Exclusion criteria:

Having infections, bone fractures, dislocations, internal and external bleedings, amputations, and nerve damages on the trauma site during the admission time Having cast or splint on the trauma site Having deep vein thrombosis confirmed by a physician Having diabetes, cardiovascular and musculoskeletal diseases, and gastrointestinal bleedings Taking anti-coagulants, analgesics, tranquilizers or sedatives, and any topical herbal extracts in the past three month History of allergic reactions to any herbal extracts History of addiction, cigarette, and alcohol abuse

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible patients will allocate to olive oil group or placebo group using simple randomization method by sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the nursing staff, who will perform the interventions, will be blinded to the contents of the

bottles. Moreover, all assessments and scorings in the two groups will done by a nurse, who will not aware of group assignments.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Aja University of Medical Sciences

Street address

Aja University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

IR.AJAUMS.REC.1397.055

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

Acute pain

ICD-10 code description

R52.0

Primary outcomes**1****Description**

Pain severity

Timepoint

At first, third, sixth and ninth days of intervention

Method of measurement

Visual analog scale

2**Description**

Dose of received analgesic

Timepoint

At first and ninth days of intervention

Method of measurement

Pain assessment checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients in the olive oil group will receive massage with olive oil twice a day for nine consecutive days. For each time, 10 mL of olive oil will apply on the site of trauma for each 50 cm² and then the trauma site will massage for five minutes.

Category

Treatment - Other

2

Description

Control group: The patients in the placebo group will receive massage with liquid paraffin twice a day for nine consecutive days. For each time, 10 mL of placebo will apply on the site of trauma for each 50 cm² and then the trauma site will massage for five minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Nahaja Hospital

Full name of responsible person

Zahra Farsi

Street address

Basij Highway, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Mostafa Shahrezaee

Street address

Aja University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran, Iran.

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Email

moshahrezayee@yahoo.com

Grant name

Not applicable

Grant code / Reference number

25069

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

Yes

Title of funding source

Artesh 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

Shiraz University of Medical Sciences

Full name of responsible person

Morteza Nasiri

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Position

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only a part of patients demographical data and main outcomes will be shared.

When the data will become available and for how long

Six months after data publishing

To whom data/document is available

Data will be available only for researchers working on academic and university associations

Under which criteria data/document could be used

Mention of study name Mention of authors name

From where data/document is obtainable

Zahra Farsi: School of Nursing, AJA University of Medical Sciences, Tehran, Iran

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

At last one month after request

Comments