Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 77 2622 5292

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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

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

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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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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