Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of light pressure stroking massage with placebo, with sesame (Sesamum indicum) oil and olive oil on pain severity and amount of received analgesic in patients with upper or lower limbs trauma

Protocol summary

Summary

This clinical trial study will do to assess the effect of light pressure stroking massage with sesame (Sesamum indicum) oil and olive oil on pain severity and amount of received analgesic in patients with upper or lower limbs trauma. Main inclusion criteria include passing at least 1 hours and at last 6 hours from trauma; lack of infection, bone fractures, dislocation, amputation, nerve damage, presence of a foreign body and internal or external bleeding; lack of cast or splint at trauma site, having appropriate perfusion in trauma site; having moderate pain during arrival time (obtaining score between 3-6 based on visual analog scale). Exclusion criteria include refusing to referral to recruitment centers for follow up more than two times consecutively; any sing of allergy and complication in patients during the study. Patients will allocate to three equal groups of light pressure stroking massage alone, light pressure stroking massage with sesame (Sesamum indicum) oil and light pressure stroking massage with olive oil according to according to table of random numbers. We will ask patients in three groups to irrigate and clean the trauma site with normal saline solution (0.9%), and after drying it with a sterile gaze, message the trauma site for 5 minutes through light pressure stroking method alone, light pressure stroking with sesame (Sesamum indicum) oil and light pressure stroking with olive oil. Intervention will do twice a day with 12 hours interval until 9 days in three groups and at the first, 3rd, 6th and 9th days of intervention, the pain severity and amount of received analgesic will assess by co-researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082814251N4**
Registration date: **2015-09-19, 1394/06/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-19, 1394/06/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Aja University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of light pressure stroking massage with placebo, with sesame (Sesamum indicum) oil and olive oil on pain severity and amount of received analgesic in patients with upper or lower limbs trauma

Public title
Effect of light pressure stroking massage with placebo, sesame (Sesamum indicum) oil and olive oil on pain severity and amount of received analgesic in patients with trauma
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age range of 15-50 years old; full consciousness and being able to read and write, passing at least 1 hours and at last 6 hours from trauma; lack of infection, bone fractures, dislocation, amputation, nerve damage, presence of a foreign body and internal or external bleeding; lack of cast or splint at trauma site, having appropriate perfusion in trauma site; free from diabetes, cardiovascular, musculoskeletal diseases and peptic ulcers; not receiving anti-coagulant drugs in 3 months ago; lack of sensitivity or allergy to the oils plant group; lack of addiction and cigarette smoking; having moderate pain during arrival time (obtaining score between 3-6 based on visual analog scale). Exclusion criteria: refusing to referral to recruitment centers for follow up more than two times consecutively; any sing of allergy and complication in patients during the study.
Age
From **15 years** old to **50 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
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Aja University of Medical Sciences Ethics Committee
Street address
Aja University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran, Iran.
City
Tehran
Postal code
Approval date
2015-08-10, 1394/05/19
Ethics committee reference number
IR.AJAUMS.REC.1394.22

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain
Timepoint
At first, third, sixth and ninth days of intervention
Method of measurement
Pain assessment scale

Secondary outcomes

1

Description
Amount of received analgesic
Timepoint
At first, third, sixth and ninth days of intervention
Method of measurement
Pain assessment checklist

Intervention groups

1

Description
We will ask patients in first intervention group to message trauma site for 5 minutes through light pressure stroking method with olive oil.
Category
Other

2

Description
We will ask patients in second intervention group to message trauma site for 5 minutes through light pressure stroking method with sesame (Sesamum

indicum) oil.

Category

Other

3

Description

We will ask patients in control group to message trauma site with placebo for 5 minutes through light pressure stroking method.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Busheher Amir-Al Momanin Hospital

Full name of responsible person

Street address

City

Busheher

2

Recruitment center

Name of recruitment center

Busheher Khatem-Al Anbia Hospital

Full name of responsible person

Street address

City

Busheher

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-chancellor of research and technology of Aja University of Medical Sciences

Full name of responsible person

Dr, Kamran Azma

Street address

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

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vic-chancellor of research and technology of Aja University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing, Aja University of Medical Sciences, Tehran, Iran.

Full name of responsible person

Zahra Farsi

Position

P.H.D of nursing education

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty