Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 May 2022

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
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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 be done by a nurse, who will not be aware of group assignments.

Placebo  
Used

Assignment  
Parallel

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

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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

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**Sponsors / Funding sources**

1. **Sponsor**

   **Name of organization / entity**
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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**
   empty

   **Type of organization providing the funding**
   Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
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Student

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Master

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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