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
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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
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

Supportive

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 months
- 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

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

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**Sponsors / Funding sources**

1

**Sponsor**

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
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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

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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**