Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Assessing the Effect of Topical Sesame Oil on Severity of Pain in Patients with Limb Trauma

Protocol summary

Study aim
Assessing the effect of topical sesame oil on pain severity caused by limb trauma in patients referring to Rasht Poursina Hospital.

Design
A randomized, triple-blind clinical trial. researchers,patients and statisticians are not aware of the study groups.

Settings and conduct
120 patients referred to the clinic of Pursina Hospital in Rasht with upper and lower extremity trauma are selected and randomly allocated to intervention group (sesame oil) and control (placebo)(Each group 60 subjects). Patient, researcher and statistician are not aware of the type of groups.Sesame oil and the placebo are encoded before using by the researcher and the patient. Data is entered to Statistical Analysis software by code.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients aged 18-60 years with full consciousness; non-penetrating trauma of the upper or lower extremities; the time of the incident is 1-6 hours before the referral; Their pain is (based on the visual scale of pain) 3 to 6. Non-inclusion criteria: Presence of fracture; bleeding; dislocation; amputation; foreign body; neural damage in injured limb; presence of fever; history of sensitivity or allergy to sesame.

Intervention groups
Intervention group : The trauma size is calculated using a flexible curved ruler and based on multiplying the length and width of the area by square centimeter.The traumatic area is washed with 100cc normal saline and poured sesame oil using a dropper on the trauma area (10 drops / 3.8cc oil per 250 cm^2 trauma area).A circular massage is given for 5 -7 minutes by finger tip.The first intervention is carried out by the researcher in the hospital and the next interventions at home by the patient (2 times a day to 3 days) after education. In the control group, the procedure is similar to the intervention group, but instead of sesame oil, the placebo is used.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180701040297N2**
Registration date: **2019-03-25, 1398/01/05**
Registration timing: **prospective**

Last update: **2019-03-25, 1398/01/05**
Update count: **0**

Registration date
2019-03-25, 1398/01/05

Registrant information

Name
Nazila Javadi-Pashaki

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-09-11, 1398/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the Effect of Topical Sesame Oil on Severity of Pain in Patients with Limb Trauma

Public title
The Effect of Topical Sesame Oil on Severity of Pain in Patients with Limb Trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the patients 18-60 years non-penetrating trauma of the upper or lower extremities occurrence of trauma between one to six hours prior to referral pain score 3-6 on visual analogue scale full consciousness
Exclusion criteria:
The presence of fractures in the injured limb The presence of bleeding at the site of the trauma dislocation of the injured limb amputation of the injured limb The presence of foreign body at the site of the trauma The presence of neurological damage in trauma location The presence of fever history of sensitivity or allergy to sesame
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Gradually and in the event of having criteria for entering the study, the samples are allocated to 2 groups of intervention and placebo by randomized blocking method based on categories of trauma size (<100 cm2 />100 cm2) and age (18-40 years / 41-60 years old).
Blinding (investigator's opinion)
Triple blinded
Blinding description
The study is a randomized three-blind randomized clinical trial. researchers, patients and statisticians are not aware of the study groups. Sesame oil and placebo bottles are coded by research colleagues. They are given to the main researcher and patient no name and with code. Based on the specified codes, the information is entered into the software and analyzed by the statistics specialist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Eastern Shahid Beheshti Boulvard
City
rasht
Province
Guilan
Postal code
93345-41938
Approval date
2019-02-04, 1397/11/15
Ethics committee reference number
IR.GUMS.REC.1397.437

Health conditions studied

1

Description of health condition studied
Patients are traumatized
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
The pain is totally evaluated 7 times; before the intervention on the first day and 30 minutes after each intervention for 3 days(Twice a day).
Method of measurement
The Visual Analogue Scale is used to measure the severity of pain that includes a continuous line with two initial and end points of zero to 10; Zero means no pain and 10 means the maximum pain intensity.

Secondary outcomes

1

Description
The amount of analgesic received during the intervention
Timepoint

At the end of the study

Method of measurement

Patient's document

Intervention groups

1

Description

Intervention group: After washing the area with normal saline, sesame oil (produced by Farabi Pharmaceutical Company) is poured on the area and then a circular massage is given with fingertip for 5 to 7 minutes. This intervention is done twice a day at home by patient and lasts for three days.

Category

Treatment - Other

2

Description

Control group: After washing the area with normal saline, placebo oil (A similar solution to the taste, color and appearance of sesame oil produced by Farabi Pharmaceutical Company) is poured on the area and then a circular massage is given with fingertip for 5 to 7 minutes. This intervention is done twice a day at home by patient and lasts for three days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Poursina Hospital

Full name of responsible person

Dr. Nazila Javadi

Street address

Poursina Intersection

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy of Guilan University of Medical Sciences

Full name of responsible person

شادمان نعمتی

Street address

خیابان نامجو - خیابان شهید سیادتی

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Technology Deputy of Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Mina Kafash Mohammadjani

Position

Postgraduate Student

Latest degree

Bachelor

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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is shared after the people became unidentifiable

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
Meta analysis

From where data/document is obtainable
Dr Nazila Javadi, Guilan University of Medical Sciences, Shahid Beheshti Nursing and Midwifery School of Rasht

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

Comments