Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topical use of sesame oil extracted from tahini (Ardeh) on pain severity in patients with upper or lower limbs trauma

Protocol summary

Study aim

The aim of this study is to investigate the effect of sesame oil extracted from tahini (Ardeh) on pain severity in patients with upper or lower limbs trauma.

Design

This randomized clinical trial study will be conducted on 120 eligible patients with upper or lower trauma referring to Rajaee Hospital, Shiraz, Iran, in 2016. Patients were randomly allocated to intervention and control groups using block randomization sampling method.

Settings and conduct

In this study, the patients with upper or lower limbs trauma who refer to emergency department of Shahid Rajaee Hospital, Shiraz, Iran in 2016 and are eligible to enter the study, will be assigned to case and control groups using block randomization. None of the patients and the nurse are aware of the type of treatment they receive. All patients are educated how to take care of their trauma site like putting cold compress on the trauma site at the first day and warm compress on the following days. Also, routine cares are implemented based on cares protocol for all patients with trauma. According to this protocol, the periphery and the center of the trauma site are irrigated and cleaned with 1000 mL sterile normal saline solution (0.9%), and then dried with a sterile gaze. At initial meeting considered as baseline and before getting any treatment, pain severity, pain sensitivity and the level of painful site heaviness are assessed, by the trained nurse using Visual Analogue Scale (VAS) and two other scales measured by a continuous line between two end-points (0 and 10). Both groups received a light massage on trauma site three times of a day with 8 h interval for 2 days duration. At the end of the second day of follow up, pain severity, pain sensitivity and the level of painful site heaviness are scored again in the both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age range of 15- 40 years; passing at least 1 hour and at most 6 hours from trauma; lack of any sign of bone fractures, internal or external bleeding, dislocation, amputation, presence of a foreign body, nerve damage, fever as well as infection; not using cast or splint at trauma site; having regional pain based on Visual Analog Scale (VAS); lack of any history of addiction, cigarette and alcohol abuse; not receiving drugs or herbal extracts which may interact with the study therapeutic protocol such as anti-coagulants and analgesics; and free from diseases that may affect the pain severity such as diabetes, cardiovascular, liver, kidney and musculoskeletal diseases. Exclusion criteria are: any sign of allergy to the sesame oil or peptic or duodenal ulcers; receiving treatment out of the study like NSAIDs; inappropriate follow up by patients; and patient's desire to withdraw in any phase of the study.

Intervention groups

All eligible patients with one or multiple blunt trauma in upper extremity (wrist, lower arm, elbow, upper arm) or lower extremity (foot, ankle, lower leg, knee, upper leg and lower trunk) will be entered the study and divided into two equal group randomly. The patients in the intervention group will receive sesame oil extracted from tahini (Ardeh) topically and the control group will use cooking oil.

Main outcome variables

We will expect that the patients who receive sesame oil extracted from tahini (Ardeh) feel less pain severity, pain sensitivity and heaviness of painful site than control group. Also, comparison of mean differences of the baseline and after 48 hours scores between control and intervention groups may show significant difference between groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171017036838N1**
Registration date: **2017-12-11, 1396/09/20**
Registration timing: **retrospective**

Last update: **2017-12-11, 1396/09/20**
Update count: **0**

Registration date
2017-12-11, 1396/09/20

Registrant information

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Maryam Gholami

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2016-04-20, 1395/02/01

Expected recruitment end date
2016-10-21, 1395/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of topical use of sesame oil extracted from tahini (Ardeh) on pain severity in patients with upper or lower limbs trauma

Public title
The effect of topical use of sesame oil extracted from tahini (Ardeh) on pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria are: age range of 15- 40 years; passing at least 1 hour and at most 6 hours from trauma; lack of any sign of bone fractures, internal or external bleeding, dislocation, amputation, presence of a foreign body, nerve damage, fever as well as infection; not using cast or splint at trauma site; having regional pain based on Visual Analog Scale (VAS); lack of any history of addiction, cigarette and alcohol abuse; not receiving drugs or herbal extracts which may interact with the study therapeutic protocol such as anti-coagulants and analgesics; and free from diseases that may affect the pain severity such as diabetes, cardiovascular, liver, kidney and musculoskeletal diseases.

Exclusion criteria:
Exclusion criteria are: any sign of allergy to the sesame oil or peptic or duodenal ulcers; receiving treatment out of the study like NSAIDs; inappropriate follow up by patients; and patient’s desire to withdraw in any phase of the study.

Age
From **15 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither the patients nor the nurse know who is getting a placebo and who is getting the treatment. Both placebo and treatment have the same color and container due to avoid bias in results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St.

City
Shiraz

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Fars

Postal code
71937-11351

Approval date
2015-05-17, 1394/02/27

Ethics committee reference number
IR.SUMS.REC.1394.34

Health conditions studied

1

Description of health condition studied
Patients with traumatic pain

ICD-10 code
R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description
Pain
Timepoint
At first day of admission (befor intervention started) and 48 hours later
Method of measurement
Numerous ruler pain

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group uses sesame oil extracted from tahini (Ardeh) topically
Category
Treatment - Other

2

Description
The control group uses cooking oil topically
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Hospital
Full name of responsible person
Maryam Gholami
Street address
Clinical Research Development Center, Nemazee Hospital, Nemazee Sq.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Gholami
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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
Shiraz 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
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Position
Manager of Clinical Research Development Center
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Person responsible for scientific inquiries

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Specialist

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General Surgery

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http://traumarc.sums.ac.ir/en/members/faculty.html

Person responsible for updating data

Contact

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Position
MSc in Biostatistics/ Statistics Expert

Latest degree
Master

Other areas of specialty/work
Biostatistics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available