Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of Lavender & Chamomile oil on the intensity of the background pain of burn patients

Protocol summary

Study aim

Main goal: to determine the effect of massage with Lavender & Chamomile oil on the intensity of the background pain of burn patients Objectives: - Comparing the intensity of background pain of burn patients in each one of Lavender & Chamomile oil, placebo, and control groups before and after intervention - Comparing the intensity of background pain of burn patients in the three groups of Lavender & Chamomile oil, placebo, and control before and after intervention

Design

A clinical non randomized trial of 105 patients, single center, parallel control and placebo groups, single blind

Settings and conduct

The burn patients in experimental group will be assigned purposefully (because of the possibility of data contamination) and control and placebo groups will be allocated by block sizes of 2. Before intervention, visual analogue scale (VAS) will be completed by the patients in 3 groups. To assess the possibility of skin sensitivity to the aromatic oils, the experimental group will undergo sensitivity test and enter to the study in case of developing no allergic reactions. The control group will receive ward routine care and the experimental group will receive routine care in addition to massage with Lavender & Chamomile oil. The placebo group will receive routine care in addition to massage with baby oil. Interventions will be employed for 20 minutes, before sleep for three consecutive sessions. After intervention, VAS will be completed by the 3 groups again. To prevent data contamination, special rooms will be assigned to experimental group by lot. Data entering in SPSS-PC will be done by a co researcher who has no interest in the results of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age more than 18 years old; Orientation to time and place; Ability to speak and comprehend Farsi language; 10-45 percent of total burn surface area (TBSA); Intact skin on some parts of leg or back; At list 72 hours past from burn injury; Burn documented as second degree and third superficial degree; Exclusion Criteria: Symptoms of septicemia; physical disability; psychological disorders; history of Asthma and allergy to the plants; history of high blood pressure and Migraine; Self-inflicted burn; Pregnancy; Sensitivity to the oils used for massage.

Intervention groups

The control group receives ward routine care. The intervention group receives massage with Lavender & Chamomile oil in addition to routine care. The placebo group receives massage with baby oil in addition to routine care.

Main outcome variables

The intensity of burn background pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171218037934N1**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Forough Rafii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2885

Email address

rafiee.f@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-05-20, 1397/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Lavender & Chamomile oil on the intensity of the background pain of burn patients

Public title
The effect of massage with Lavender & Chamomile oil on burn pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
More than 18 years old Orientation to time and place Ability to speak and comprehend Farsi language 10-45 percent of total burn surface area (TBSA) Intact skin on some parts of leg or back At list 72 hours after burn injury Burn documented as second degree and third superficial degree
Exclusion criteria:
Symptoms of septicemia according to patient's record Physical disability Psychological disorders History of Asthma and allergy to the plants History of high blood pressure and Migraine according to the patient's record Self-inflicted burn Pregnancy Skin donors on legs and back during the study Sensitivity to the oils used for massage during the study
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants aren't informed of their assignment to the 3 groups(experimental, control, placebo). Data will be entered to SPSS by a co researcher who has not any interest in the results of the study.
Placebo
Used
Assignment
Parallel
Other design features
Regarding the possibility of data contamination in control and placebo groups by the scent of aromatic oils, the experimental group will be recruited according to their willingness and the inclusion criteria from randomly selected rooms.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway,Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-12-17, 1396/09/26
Ethics committee reference number
IR.IUMS.REC 1396.32050

Health conditions studied

1

Description of health condition studied
Pain due to burn trauma
ICD-10 code
G89.11
ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Intensity of burn background pain score on VAS
Timepoint
Before intervention and after 3 sessions of intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Massage with 10-15 milliliters of lavender & chamomile oil using effleurage techniques will be used for the intact skin regions (legs and back) of the intervention group during a 20 minute session before sleep for 3 sessions. To prevent allergic reactions, 2 drops of lavender and 2 drops of chamomile oil (produced by Zardband Co.) in 30 milliliters of Grape Core Base Oil will be used.
Category
Other

2

Description
Control group: The control group receives routine ward care.
Category
N/A

3

Description
Intervention group 2: Massage with 10-15 milliliters of baby oil using effleurage techniques will be used for the intact skin regions (legs and back) of the placebo group during a 20 minute session before sleep for 3 sessions.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahid Motahary burn hospital
Full name of responsible person
Parviz Namazi
Street address
Sahid Motahary burn hospital, in front of Khatam Alanbia hospital, Rashid Yasami Ave., Vali-asr Ave.
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not included in the
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Morteza Naserbakht
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Beside the Milad Tower, Shahid Hemmat Highway
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Web page address
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Forough Rafii
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical-surgical nursing
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Person responsible for updating data

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Web page address
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
No - There is not a plan to make this available