

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 Raffi

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

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget 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
Alania hospital, Rashid Yasami Ave., Vali-asr Ave.

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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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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 Raffi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical-surgical nursing

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

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Full name of responsible person

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Position

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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