

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of the Effectiveness of Inhaling Sour Lemon Essential Essence and Placebo on the Level of Consciousness in Adult Patients with Mild to Moderate Decreased Level of Consciousness

Protocol summary

Study aim

Investigating the effect of lemon essential oil inhalation on the level of consciousness of adult patients with mild to moderate loss of consciousness admitted to special departments of the hospital

Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized, phase 2-3 on 68 patients, is used for randomization by pouring paper into the number of special sections and randomly picking them.

Settings and conduct

The research population will be adult patients with reduced level of consciousness hospitalized in the special care units of Shahid Rajaei Hospital who meet the conditions for entering the study and declare their informed consent to participate in the study. Then, the special departments are divided into 2 groups by random allocation method, and half an hour before each intervention, the Glasgow coma score of the patients will be checked and the intervention will be performed, and after each intervention, the GCS will be measured. The person who evaluates the LOC and the person who analyzes the data in this study are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with decreased level of consciousness, that at least one week has passed since their injury or brain damage, (GCS 9-14) due to Head Trauma, Neurological Diseases, Informed consent of the patient or her/his first degree relatives to participate in the study; Exclusion criteria: receiving sedatives, limb paralysis such as Spinal Cord Lesions, Intubated or tracheostomy patients, allergies to plant extracts.

Intervention groups

The intervention groups inhale 5 drops of lemon essential oil on a cotton pad in a porous box at a distance of 20-40 cm, 3 times a day and for 20 minutes each time, during 5 days. The control group will inhale

normal saline under the same conditions.

Main outcome variables

Glasgow coma score

General information

Reason for update

Changing the research environment and study method during the implementation of intervention according to the existing conditions

Acronym

IRCT registration information

IRCT registration number: **IRCT20221203056699N1**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **1**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Zahra Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3720 5242

Email address

zahra_ranjbar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-02-19, 1401/11/30
Actual recruitment start date
2023-02-19, 1401/11/30
Actual recruitment end date
2023-06-20, 1402/03/30
Trial completion date
2023-06-20, 1402/03/30

Scientific title
Comparison of the Effectiveness of Inhaling Sour Lemon Essential Essence and Placebo on the Level of Consciousness in Adult Patients with Mild to Moderate Decreased Level of Consciousness

Public title
Inhaling Sour Lemon Essential Essence and Level of Consciousness

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with decreased level of consciousness , that at least one week has passed since their injury or brain damage. 18 years old and older age Mild to Moderate level of consciousness disorder (GCS 9-14) due to Head Trauma, Neurological Diseases and Stroke. Informed consent of the patient or her/his first degree relatives to participate in the study.

Exclusion criteria:

Patients with decreased level of consciousness, as a result of receiving sedatives. Patients with limb paralysis such as Spinal Cord Lesions, due to movement disorders. Intubated or tracheostomy patients. Respiratory allergies or allergies to plant extracts. Problems related to smell and nose injury. Participating in previous studies receiving Complementary and Alternative Medicine interventions from one week before our intervention.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **68**
Actual sample size reached: **68**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

The intervention is carried out by a research assistant other than the researcher evaluating the Glasgow coma score before and after the intervention. As a result, the impact assessment researcher is unaware of the type of intervention. Also, as much as possible, the clinical

caregiver is kept unaware of the type of intervention. The data analyst will do his work based on the anonymous codes and does not know the type of intervention performed on each code that is a patient. The legal guardian of the patient is fully aware of the study and its purpose, but they are not informed about the type of essential oil (lemon or normal saline).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand St., University of Medical Sciences central building, 7th floor, Research and Technology Vice-Chancellor

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.079

Health conditions studied

1

Description of health condition studied

Decrease Level of Consciousness

ICD-10 code

G96.9

ICD-10 code description

Disorder of central nervous system, unspecified

Primary outcomes

1

Description

Level of Consciousness

Timepoint

The level of consciousness will be measured at the beginning of the study (before the start of the intervention) and every first 5 days, as well as on the eighth day (three days after the last day of the

intervention), half an hour before each intervention and 10 minutes after each intervention.

Method of measurement

Glasgow coma score

Secondary outcomes

empty

Intervention groups

1

Description

intervention will be done within 5 days; 3 times a day and 20 minutes each time (in order to compensate for limitation of the hospitalization time, the frequency of the intervention has been increased to three times). In this regard, for the intervention group, the researcher first placed cotton soaked with 5 drops of 68.2% lemon essential oil from Kashan Barij essence medicine company, in a porous box at a distance of 20-40 cm from the patient and every day at 8:30, 12:30, 16:30 will be used and inhaled.

Category

Treatment - Other

2

Description

within 5 days; 3 times a day and 20 minutes each time, for the control group, by the researcher, cotton soaked with 5 drops of normal saline (as a placebo) was placed in a porous box at a distance of 20-40 cm from the patient and every day at 8:30, 12 :30, 16:30 will be used and inhaled.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajayi hospital

Full name of responsible person

Golnar Sabetian

Street address

Chamran Blvd, before Niayesh Ave, Rajayi hospital

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3636 4001

Email

rajaehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Roxana Jan Ghorban

Street address

Namazi square, Hazrat Fatemeh nursing college

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Fax

Email

janghorban@sums.ac.ir

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

Full name of responsible person

Zahra Ranjbar

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Zand Ave, Namazi Square, Hazrat Fatemeh Nursing College

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

zahra_ranjbar@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahnaz Rakhshan

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Namazi Square, Hazrat Fatemeh Nursing College

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

rakhshanm@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Ranjbar

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Namazi Square, Hazrat Fatemeh Nursing College

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

zahra_ranjbar@sums.ac.ir

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

No - There is not a plan to make this available

Data Dictionary

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