Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Effect of Citrus Aurantium aroma on pain and physiological criteria of patients undergoing hand reconstructive surgery hospitalized in intensive care unit

Protocol summary

Study aim
Determining effect of Citrus Aurantium aroma on pain and physiological criteria

Design
A blinded quasi-experimental study with a control group. 76 patients with inclusion criteria were randomly assigned to Citrus Aurantium or placebo

Settings and conduct
Pain and physiological parameters are measured before the intervention. In the operating room recovery, the researcher, without knowing the type of solution (Citrus Aurantium with a concentration of 40% or placebo), pour the solution on the pad 2 × 2 . Pad soaked in a solution of(Citrus aurantium or placebo) is taken at a distance of 5 cm from the nose up to ten breaths and then that pad is attached to the patient's collar. At the end of half an hour, the pain rating and physiological criteria are checked and recorded. After transferring the patient from the recovery room to the intensive care unit while the pad is attached to the patient's collar, one hour after the second record, the pain rating and physiological criteria are checked again and is recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years old ,after reconstructive hand surgery, the patient should be transferred to the intensive care unit,alertness and ability to understand and express pain, informed consent for research , , healthy sense of smell. No entry :having allergies, drug addiction , uncontrolled diabetes and neuropathy, mental illness and cognitive disorders.

Intervention groups
Citrus Aurantium solution with a concentration of 40%, 0/4 ml placebo solution 0/4 ml

Main outcome variables
pain ; Pulse; Breathing; blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200811048374N1**
Registration date: **2021-03-01, 1399/12/11**
Registration timing: **retrospective**

Last update: **2021-03-01, 1399/12/11**
Update count: **0**

Registration date
2021-03-01, 1399/12/11

Registrant information

Name
farideh askari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-11-12, 1399/08/22

Actual recruitment start date
2020-08-22, 1399/06/01

Actual recruitment end date
2020-11-12, 1399/08/22

Trial completion date
2020-11-12, 1399/08/22

Scientific title
The Effect of Citrus Aurantium aroma on pain and physiological criteria of patients undergoing hand reconstructive surgery hospitalized in intensive care unit

Public title
Citrus Aurantium aroma on pain and physiological criteria

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patient undergoing reconstructive hand surgery who are is transferred to the intensive care unit after surgery The patient is alert and awake and the ability to understand and express the pain and the patient is able to cooperate Age range over 18 years based on the year of birth Healthy sense of smell according to the patient

Exclusion criteria:
Drug addiction (according to the patient statement and the file) Uncontrolled diabetes and neuropathy Mental illness and cognitive disorders based on the records in patient's file History of respiratory allergies, asthma, allergic rhinitis and allergies to plant products according to the patient

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the required number of samples, a total of 76 patients were estimated، 38 patients in the experimental group and 38 patients in the control group. Randomization was performed by simple method with Excel software with 76 numbers in two groups and in each group 38 numbers were placed randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
there are glass containers in the similar package with the code ، containing equal amounts of placebo and Citrus Aurantium . The researcher without knowing the type of solution of each container, randomly selected one of the containers and used its solution for the research sample with inclusion criteria and then recorded the data. The samples were not aware of the type of solution used.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahed university

Street address
Persian Gulf High Way Shahed university

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2020-04-28, 1399/02/09

Ethics committee reference number
IR.SHAHED.REC.1399.019

Health conditions studied

1

Description of health condition studied
Pain and physiologic criteria

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
Before intervention . Half an hour after the intervention and one and a half hours after the intervention

Method of measurement
Visual analog scale for pain

2

Description
pulse - respiration- Blood Pressure (systolic and diastolic)

Timepoint
Before intervention . Half an hour after the intervention and one and a half hours after the intervention

Method of measurement
records on monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery in the recovery room, while the patient is is conscious , before performing the intervention, 1- pain and physiological parameters are measured. 2-The researcher, Citrus Aurantium solution pours on the pad 2 * 2(0.4 ml),the pad is taken a distance of 5 cm from the nose up to ten breaths and then the pad was attached to the patient's collar, after half an hour, pain and physiological measurements are checked and recorded. 3-After transferring the patient from the recovery room to the intensive care unit while the pad is attached to the patient's collar, one hour after the second recording, the pain and physiological criteria are checked and recorded .

Category

Other

2

Description

Control group: After surgery in the recovery room, while the patient is is conscious , before performing the intervention, 1- pain and physiological parameters are measured. 2-The researcher,placebo solution pours on the pad 2 * 2(0.4 ml), the pad is taken a distance of 5 cm from the nose up to ten breaths and then the pad was attached to the patient's collar, after half an hour, pain and physiological measurements are checked and recorded. 3-After transferring the patient from the recovery room to the intensive care unit while the pad is attached to the patient's collar, one hour after the second recording, the pain and physiological criteria are checked and recorded .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Fatemeh Hospital affiliated to Iran University of Medical Sciences

Full name of responsible person
Noorahmad Latifi

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yosefabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
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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
Shahed University

Proportion provided by this source
50

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
Shahed University

Full name of responsible person
Nasrin Alaee

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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