Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Investigation on the effectiveness inhalation aromatherapy with Rosa damascena essential versus placebo on the anxiety and sleep quality of patients with burns. a double blinded randomized clinical trial

Protocol summary

Study aim
The effect of inhaled aromatherapy with rose essential oil on anxiety and sleep quality of burn patients.

Design
This study is a controlled clinical trial in which 60 patients admitted to the burn ward who are eligible for the study are randomly assigned to be divided into two groups: intervention and control.

Settings and conduct
This study is available as a randomized clinical trial of patients admitted to the burn ward of Valiasr Hospital in Arak and is available to patients who are eligible to enter the study. Numerous studies have been performed on the effectiveness of aromatherapy in burn patients who have reported different results. In this study, 60 patients admitted to the burn ward of Valiasr Hospital affiliated to Arak University of Medical Sciences are randomly assigned to two control and intervention groups. In the intervention group, patients inhaled five drops of 40% essential oil in distilled water, while in the control group, they inhaled 5 drops of distilled water as a placebo. The quality of sleep and the anxiety questionnaire are checked using a questionnaire. The participant and the data collector are kept blind to which participant is in which group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: a) age15 to 65 years؛ b) burns degree of 2 and 3 with 15 to 65 percent burn level; c) stability of hemodynamic status. Exclusion criteria: a) Lack of patient cooperation during the intervention for any reason; b) creation dangerous conditions of disease during the intervention.

Intervention groups
60 burn patients will be selected as available samples and will be divided into two groups using intervention and control blocks.

Main outcome variables
Anxiety; sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180519039711N7**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date
2021-04-12, 1400/01/23

Registrant information

Name
Mohamad Golitaleb

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3506

Email address
m.golitaleb@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-08, 1399/11/20

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation on the effectiveness inhalation aromatherapy with Rosa damascena essential versus placebo on the anxiety and sleep quality of patients with burns. a double blinded randomized clinical trial

Public title
The effect of inhaled aromatherapy with rosa damascena essential oil on anxiety and sleep quality of burn patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 15 to 65 years Burns 2 and 3 with burns 15 to 65 percent Stability of hemodynamic status

Exclusion criteria:
Lack of patient cooperation during the intervention For whatever reason, dangerous disease conditions arise during the intervention

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using random blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not be aware of the type of intervention. Also, the patient nurse will not know the type of intervention. Therefore, the study will be conducted in both directions.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of kashan University of Medical Sciences

Street address
Vice-Chancellor for Research, Kashan University of Medical Sciences, Ravand Blvd., Kashan, Iran

City
kashan

Province
Isfehan

Postal code
8715988141

Approval date
2021-01-27, 1399/11/08

Ethics committee reference number
IR.KAUMS.REC.1399.050

Health conditions studied

1

Description of health condition studied
Burns

ICD-10 code
M61.329

ICD-10 code description
Calcification and ossification of muscles associated with burns, unspecified upper arm

2

Description of health condition studied
anxiety

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

3

Description of health condition studied
sleep quality

ICD-10 code
F51.9

ICD-10 code description
Sleep disorder not due to a substance or known physiological condition, unspecified

Primary outcomes

1

Description
sleep quality

Timepoint
At the beginning of the study and 72 hours after the intervention

Method of measurement
St. Mary's Hospital Sleep Quality Questionnaire

2

Description
Anxiety

Timepoint
At the beginning of the study and 72 hours after the intervention
Method of measurement
The State-Trait Anxiety Inventory -Spielberger

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: The researcher will use the scent of rosemary to affect patients' anxiety and sleep quality. Every night and for three nights, the researcher puts three drops of rosehip extract on a paper towel and attaches it to the patient's bedside table with a pin. The napkin stays on the bed for 8 hours (from 10 pm to 6 am). After three nights of aromatherapy, on the morning of the fourth day of the study, the anxiety and sleep quality of the participants of the intervention group are measured.
Category
Treatment - Drugs

2

Description
Control group: Control group: In the control group, the researcher drips three drops of distilled water as a placebo on a paper towel and connects it to the patient's bedspread near his head with a pin. The napkin stays on the bed for 8 hours (from 10 pm to 6 am). After three nights, on the morning of the fourth day of study, anxiety and sleep quality of the participants in the control group are measured.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Mohamad golitaleb
Street address
Valiasr Hospital .Valiasr Square
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
pr_valieasr@arakmu.ac.ir
Web page address
https://arakmu.ac.ir/valiasrhos

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafsheh
Street address
Vice-Chancellor for Research, Kashan University of Medical Sciences, Ravand Blvd., Kashan,
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 2999
Fax
+98 31 5557 5057
Email
Research@kaums.ac.ir
Web page address
http://kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Neda Mirbagher Ajorpaz
Position
Associate Professor
Latest degree
Ph.D.

Other areas of specialty/work
Nursery
Street address
kashan University of Medical Sciences. Ravand Blvd., Kashan
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5554 0021
Fax
+98 31 5554 6633
Email
mirbagher_n@kaums.ac.ir
Web page address
http://nursing.kaums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Golitaleb
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Arak University of Medical Sciences. Basij square. Arak
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3503
Fax
+98 86 3417 3503
Email
mohamadgolitaleb@gmail.com
Web page address
http://arakmu.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Golitaleb
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Arak University of Medical Sciences. Basij square. Arak
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3503
Fax
+98 86 3417 3503
Email
mohamadgolitaleb@gmail.com
Web page address
http://arakmu.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.
When the data will become available and for how long
Start the access period 6 months after the results are published.
To whom data/document is available
Researchers and people working in nursing education as well as nursing clinical staff.
Under which criteria data/document could be used
The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.
From where data/document is obtainable
Mohamad golitaleb,Department of critical care nursing,school of nursing,Arak university of medical sciences E mail:Mohamadgolitaleb@gmail.com Tel:+989379366279
What processes are involved for a request to access data/document
After ensuring that the data applicant is in the nursing

field, we will be immediately responded to the request form by email.

Comments