Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effects of Inhaling Rose Aroma and Benson's Relaxation Technique on Pain Anxiety in Burn Patients

Protocol summary

Study aim
Comparing the Effects of Inhaling Rose aroma and Benson's Relaxation Technique on Pain Anxiety in Burn Patients

Design
Clinical trial with control group, community-based and pragmatic, with parallel groups, single-blind and randomized

Settings and conduct
This study is performed on patients hospitalized in the burn ward of Shahid Motahari Hospital. It is a single-blinded clinical trial in which the researcher's assistant is blind to the study groups and registers pain scores according to the BSPAS questionnaire. 4 groups: first group: aroma therapy, second group: Benson's relaxation method, third group: both aroma and Benson's Relaxation, fourth group: control group receiving common treatments. Data collection: demographic information form and pain anxiety questionnaire.

Participants/Inclusion and exclusion criteria
-Burn patient of 18 to 60 years old males and females -Hospitalized in the burn ward -Contain Second degree burns or more -Without inhalation, electrical or self-immolation

Intervention groups
1. In the first group patients have to Inhale rose aroma for 20 minutes for three consecutive days each day for 45 minutes before changing dressings daily 2. In the second group, Benson's Relaxation, patients perform 20 minutes a day each day 45 minutes before the daily dressing for three consecutive days 3. Inhaling Rose aroma and Benson's Relaxation Group before the daily dressing for three consecutive days for 30 minuets 4. Control group with common treatment procedures

Main outcome variables
pain anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171212037843N1**
Registration date: **2018-06-04, 1397/03/14**
Registration timing: **retrospective**

Last update: **2018-06-04, 1397/03/14**
Update count: **0**

Registration date
2018-06-04, 1397/03/14

Registrant information

Name
Leila Daneshpazhoh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2632 9241

Email address
daneshpazhoh.l@tak.iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the Effects of Inhaling Rose Aroma and Benson's Relaxation Technique on Pain Anxiety in Burn Patients

Public title
Comparing the Effects of Inhaling Rose Aroma and Benson's Relaxation Technique on Pain Anxiety in Burn Patients

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Burn patients with age of 18-60 years both female and male Patients admitted after 72 hours past their burn Patients with second degree burn or more Verbal communication ability No electrical and inhalation burn or self-immolation Lack of mental disorder Lack of allergy to rose according to patients' self-report No history of allergy or respiratory problems according to patients' self-report No impaired hearing interfering the process of Benson's Relaxation Technique

Exclusion criteria:

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The method for assigning samples in groups is a fixed non-Permuted Block randomization with block sizes of 4 and 1:1 ratio. In each ward of the two rooms, the samples are assigned to two groups by four blocks random in the groups, and the same is done for the other two groups of the other two rooms. So the patients in the two groups without fragrance treatment (under Benson relaxation alone or as a control) with rose aroma in groups with fragrance treatment (including inhaling rose aroma alone, as well as the combination of two interventions) will not be affected by each other. This means that the allocation of samples for two groups of Benson relaxation and control from two rooms of each ward and assignment of samples to the other two groups of the other two rooms of the same wards will be carried out with a four-block random. In this method, different states of the two groups are written on the card and each one is placed in an envelope in a non-transparent package. These packs will be placed inside a folder. After identifying the research units, the collaborator of the research (unknowing study and groups) by removing one of the envelopes will identify each patients included in the study and grouped accordingly. This process will be continued until all the cards are removed from the folder and again returned to the folder and this random selection is repeated to provide the desired sample size.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single-blind clinical trial. The unaware researcher of the studied groups recorded pain anxiety scores based on patients' response to the BSPAS Burn Pain Anxiety Inventory.

Placebo
Not used

Assignment
Parallel

Other design features

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, Hemmat High

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-01-18, 1396/10/28

Ethics committee reference number
IR.IUMS.REC1396.9511449003

Health conditions studied

1

Description of health condition studied
Burns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain Anxiety Score in a Burn Questionnaire: BSPAS

Timepoint
1-Before the intervention and dressing, 2- Immediately after the intervention before dressing and 3- Immediately after dressing

Method of measurement
Burn Pain Anxiety Questionnaire : BSPAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Inhaling 5 drops of 40% rose aroma (Yas Sepidosh Trading Company) for 20 minutes in 3 consecutive days about 30 to 45 minutes before changing dressings daily
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Hospital
Full name of responsible person
Leila Daneshpazhooh
Street address
Yasemi St .Motahari hospital
City
Tehran
Province
Tehran
Postal code
1996714353
Phone
+98 21 8877 0031
Email
daneshpazhoh.l@tak.lums.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Kazem Malakouti
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8877 0031
Email
malakoutik@gmail.com
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
Leila Daneshpazhooh
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Motahari Hospital, Yasemi St, Valiasr St
City
Tehran
Province
Tehran
Postal code
1996714353
Phone
+98 21 8877 0031
Email
daneshpazhoh.l@tak.lums.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Tahereh Najafi Ghezeljeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Iran University of Medical Sciences,Hemat Highway
City
Tehran
Province

Tehran

Postal code
1449614535

Phone
+98 21 8877 0031

Email
taherehpaniz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Leila Daneshpazhooh

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Motahari Hospital, Shahid Yasemi St, Shahid Valiasr St

City
Tehran

Province
Tehran

Postal code
1996714353

Phone
+98 21 8877 0031

Email
daneshpazhoh.l@tak.lums.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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Data were collected in questionnaires and statistical analysis was done.

When the data will become available and for how long
Starting the access period 1 year after publication.

To whom data/document is available
It is accessible to researchers working in academic and scientific institutions and those engaged in the industry.

Under which criteria data/document could be used
In order to help other researchers and compare with other similar data.

From where data/document is obtainable
To receive data by email: daneshpazhoh.l@tak.iums.ac.ir and refer to address : Shahid Motahari Hospital, Shahid Yasemi St, Valiasr St. Leila Daneshpazhooh.

What processes are involved for a request to access data/document
by email or refer to presented address and Data is available to researchers in less than one month .

Comments