Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effects of painting therapy, aromatherapy with Rosa damascena Mill., and aromatherapy with placebo on the management of anxiety, pain, and complications of tonsillectomy among children aged 6-12 years

Protocol summary

Study aim
Comparing effects of painting therapy, aromatherapy with Rosa damascena Mill., and aromatherapy with placebo on the management of anxiety, pain, and complications of tonsillectomy

Design
A controlled, parallel-group, unblinded, randomized, phase 3 clinical trial of 84 children. Randomization will be done through concealed randomized sequences.

Settings and conduct
This study will be conducted on 84 children candidates for tonsillectomy in three teaching hospitals of Khuzestan (Shahid Beheshti and Alavi in Abadan and Valiasr in Khorramshahr). The participants will be assigned to three equal groups of 28 samples by random number generation software. Due to the different nature of interventions, it will not be possible to blind the participants. However, the same product bottles will be used in the aromatherapy groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being 6-12 years old, admitting to hospital night before the surgery, undergoing tonsillectomy under general anesthesia and by dissection and snare approach, having class I and II of American Society of Anesthesiology (ASA) Exclusion criteria: A history of sensitivity to scents and perfumes, having a disorder in the sense of smell, participation in previous courses of painting therapy or aromatherapy, a history of tonsillectomy for another child in the family

Intervention groups
Participants in all three groups will receive routine surgical care. However, the participants of painting therapy group will receive a program based on painting therapy and the participants of aromatherapy groups will receive inhalation of the essential oil of Rosa damascena Mill. or placebo. In all three groups, two 20-minute sessions and three 20-minute sessions will be performed in hospital and after hospital discharge, respectively.

Main outcome variables
anxiety, pain, and complications of tonsillectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130803014251N10**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date
2024-01-28, 1402/11/08

Registrant information

Name
MORTEZA NASIRI

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 77 2622 5292

Email address
nasiri.m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-19, 1402/10/29

Expected recruitment end date
2024-05-18, 1403/02/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of painting therapy, aromatherapy with Rosa damascena Mill., and aromatherapy with placebo on the management of anxiety, pain, and complications of tonsillectomy among children aged 6-12 years

Public title
Comparing the effects of painting therapy and aromatherapy with Rosa damascena Mill. on the management of anxiety, pain, and complications of tonsillectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Desiring to participate in the research and complete the written consent form Being 6-12 years old Admitting to the hospital the night before the surgery Undergoing tonsillectomy under general anesthesia and by dissection and snare approach Having class I and II of the American Society of Anesthesiology (ASA) Accessing to a smartphone to participate in follow-up sessions after hospital discharge
Exclusion criteria:
A history of sensitivity to scents and perfumes Having a disorder in the sense of smell Presence of cognitive or mental disorders, heart diseases, and chronic pain based on medical records Participation in previous courses of painting therapy or aromatherapy A history of surgery and anesthesia A history of tonsillectomy for another child in the family
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
First, each admitted participant will be allocated a number from 1-84. Then, participants will be stratified by age using the stratified method. Subsequently, participants of each stratify will be equally assigned to painting therapy, aromatherapy with Rosa Damascena Mill., and aromatherapy with placebo groups, utilizing the Stat Trek software with a random number generator. Randomization will be accomplished by a researcher assistant, who will be unaware of the aim of this trial and will be the only individual with access to group allocations.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Abadan University of Medical Sciences
Street address
Building of Abadan University of Medical Sciences, Zulfaqari, 30M street, Abadan, Khuzestan province, Iran
City
Abadan
Province
Khouzestan
Postal code
6319811154
Approval date
2023-08-05, 1402/05/14
Ethics committee reference number
IR.ABADANUMS.REC.1402.070

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

2

Description of health condition studied
Surgical complications
ICD-10 code
Y83.9
ICD-10 code description
Surgical procedure, unspecified as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

3

Description of health condition studied
Acute tonsillitis
ICD-10 code
J03.9
ICD-10 code description
Acute tonsillitis, unspecified

4

Description of health condition studied
Pain
ICD-10 code
R07.0
ICD-10 code description
Pain in throat

Primary outcomes

1

Description
Tonsillectomy-induced anxiety
Timepoint
4 steps: 1) the night before surgery in the hospitalized ward: before the start of the first intervention session as the first pre-test, 2) the day of surgery immediately before transferring the samples from the hospitalized ward to the operating room department: as the first post-test, 3) The day of surgery at the beginning of admitting the samples in the waiting room before surgery: before the start of the second intervention session as the second pre-test, 4) the day of surgery when lying on the surgery bed and immediately before induction of anesthesia: as the second post-test.
Method of measurement
Modified Yale preoperative anxiety scale

2

Description
Pain
Timepoint
The first three days after discharge from the hospital
Method of measurement
Numerical pain rating scale (or Wong-Baker faces pain rating scale)

Secondary outcomes

1

Description
Complications of tonsillectomy
Timepoint
The first three days after discharge from the hospital
Method of measurement
Researcher-made checklist

Intervention groups

1

Description
First Intervention group: The participants in the first experimental group will receive surgical preparation and perioperative care based on the standard protocols of the recruitment hospitals. Additionally, they will receive a painting therapy program in two 20-minute sessions in the hospital and three 20-minute sessions after hospital discharge.
Category
Treatment - Other

2

Description
Second Intervention group: The participants in the first experimental group will receive surgical preparation and perioperative care based on the standard protocols of the recruitment hospitals. Additionally, they will receive an inhalation aromatherapy with two drops of Rosa damascena Mill. essence in two 20-minute sessions in the hospital and three 20-minute sessions after hospital discharge.
Category
Treatment - Other

3

Description
Control group: The participants in the control group will receive surgical preparation and perioperative care based on the standard protocols of the recruitment hospitals. Additionally, they will receive an inhalation aromatherapy with two drops of placebo (distilled water) in two 20-minute sessions in the hospital and three 20-minute sessions after hospital discharge.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Masoomeh Asadi
Street address
Ayatollah Taleghani avenue, Khorramshahr, Khuzestan province, Iran
City
Khorramshahr
Province
Khouzestan
Postal code
6418733891
Phone
+98 61 5354 4800

Email
M.asadi@abadanums.ac.ir

2

Recruitment center
Name of recruitment center
Alavi hospital
Full name of responsible person
Masoomeh Asadi
Street address
In front of Islamic Azad University, Abadan, Khuzestan province, Iran
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 939 751 7636
Email
M.asadi@abadanums.ac.ir

3

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Masoomeh Asadi
Street address
Shahid Beheshti avenue, Abadan, Khuzestan province, Iran
City
Abadan
Province
Khouzestan
Postal code
63197 15473
Phone
+98 61 5332 3094
Email
M.asadi@abadanums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Mohammadi
Street address
Building of Abadan University of Medical Sciences, Zulfaqari, 30M street, Abadan, Khuzestan province, Iran
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Email
Mohammadi-sm@ajums.ac.ir
Web page address
https://abadanums.ac.ir/Portal/Home/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Abadan 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
Abadan University of Medical Sciences
Full name of responsible person
Masoomeh Asadi
Position
Instructor, Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Building of Abadan University of Medical Sciences, Zulfaqari, 30M street, Abadan, Khuzestan province, Iran
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Email
M.asadi@abadanums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Morteza Nasiri

Position
Assistant professor of nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No.17, Fardanesh Alley, Qods Street, Enqelab Street, Tehran, Iran

City
Tehran

Province
Khouzestan

Postal code
44361-14177

Phone
+98 21 8898 2905

Email
mnasiri@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Abadan University of Medical Sciences

Full name of responsible person
Masoomeh Asadi

Position
Instructor, Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Building of Abadan University of Medical Sciences, Zulfaqari, 30M street, Abadan, Khuzestan province, Iran

City
Abadan

Province
Khouzestan

Postal code
6319811154

Phone
+98 61 5338 4004

Email
M.asadi@abadanums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Only a part of patients' demographical data and main outcomes will be shared.

When the data will become available and for how long
After the publishing of the results

To whom data/document is available
Data will be available only for researchers working on academic and university associations.

Under which criteria data/document could be used
Mention of study details and authors name

From where data/document is obtainable
Morteza Nasiri: Department of Operating Room, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran

What processes are involved for a request to access data/document
Information will provide via the following email upon request. Mortezanasiri.or87@yahoo.com

Comments