

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Effect of Auriculotherapy and Aromatherapy with damask rose essential oil on Preoperative Anxiety in Children

Protocol summary

Study aim

Effect of Auriculotherapy and Aromatherapy on Preoperative Anxiety

Design

The randomized clinical trial, controlled, parallel groups, community-based, sample size: 93

Settings and conduct

Location: Akbar hospital, the children are selected by convenience method in this study and then are randomly divided into three groups of aromatherapy, auriculotherapy and control. At first, children's anxiety levels in the three groups are determined by the researcher and then they are placed in the auriculotherapy group and aromatherapy group and control group. 30 minutes after the intervention and before the child is transferred to the operating room, the anxiety level is again measured. The control group receives the routine program. The level of anxiety in the control group is determined 30 minutes later and before being transferred to the operating room. .

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Age of 12-6 years, candidate for minor surgery with general anesthesia, lack of chronic disease, absence of lesion or rash on the ears, no history of respiratory disease and respiratory sensitivity criteria for existing the study: unwillingness to continue participating in the study, the emergence of any special medical condition

Intervention groups

Acupressure group: in the operation day, seeds are installed for 30 minutes in the Shen Men point, relaxation, trunkolizer and endocrine in the non-dominant ear to cause continuous pressure, and during installation, each one of the seeds is held for 2 minutes on each of the designated points with a finger. The aromatherapy group: they are treated for 20 minutes with five drops of damask rose essential oil of 40% that is threaded on a 10 × 10 cotton thread. Control group: routine actions are performed.

Main outcome variables

Reduce anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170624034737N1**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **retrospective**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 506 7739

Email address

zareia3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Auriculotherapy and Aromatherapy with damask rose essential oil on Preoperative Anxiety in Children

Public title
Effect of Auriculotherapy and Aromatherapy on Anxiety in Children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 12-6 years undergo minor surgery
Exclusion criteria:
History of allergy and respiratory disease in the aroma group
History of skin allergy in the auriculotherapy group

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **93**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation block (n=3) method is used to allocate the individuals to the control and intervention groups. In this case, three blocks were determined with the help of the random numbers table. For each selected number, which was between 0-4, the ABC and if the number was 5 - 9, we write the term BCA and 10 - 14 CAB, together with each other as a string. For example, if the numbers selected are 7, 4, 6, 11, 14 and 3, the terms are: BCA - ABC - BCA - CAB - CAB - ABC. Thus, the first child in Group B (the Aromatherapy) and the second in Group C(Control) and a 3th , 4th in Group A ,5th in Group B and sixth in C and the 7th in group B, eighth in Group A and the 9th in Group A and the 10th case in group C Will continue as well as the sample size is sufficient.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology University,
Building Qureshi, Daneshgah St, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91775-1365

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.MUMS.REC.1397.096

Health conditions studied

1

Description of health condition studied

Pre operative Anxiety in Children

ICD-10 code

F93.0

ICD-10 code description

Separation anxiety disorder of childhood

Primary outcomes

1

Description

Child anxiety

Timepoint

Before and after the intervention, before transfer to surgery room

Method of measurement

Modifed Yale Preoperative Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acupressure group: in the operation day, seeds are installed for 30 minutes in the Shen Men point, relaxation, trunkolizer and endocrine in the non-dominant ear to cause continuous pressure, and during installation, each one of the seeds is held for 2 minutes on each of the designated points with a finger.

Category

Treatment - Devices

2

Description

Intervention group: The aromatherapy group: they are

treated for 20 minutes with five drops of damask rose essential oil of 40% that is threaded on a 10 × 10 cotton thread.

Category

Treatment - Drugs

3

Description

Control group: no intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's hospital

Full name of responsible person

Azam Zarei

Street address

Front side Shahid Kaveh 14 Ave, Shahid Kaveh Blevd

City

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Razavi Khorasan

Postal code

9177897157

Phone

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Email

zareia3@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Deputy of Research and Technology University,
Building Qureshi, Daneshgah St, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Azam Zarei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Daneshgah St,Ibn-e Sina St, School of Nursing and
Midwiferyvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Soheila Karbandi

Position

Faculty member of School of Nursing and Midwifery
Mashhad

Latest degree

Master

Other areas of specialty/work

Nursing Education; Pediatric Nursing

Street address

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Azam Zarei
Position
MSc pediatric Nursing student
Latest degree
Bachelor
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

Not applicable

Data Dictionary

Not applicable