

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of aromatherapy with Neroli essential oil on dental anxiety in children during dental treatment

Protocol summary

Study aim

Determining the effect of aromatherapy with Neroli essential oil on stress and anxiety control of children aged 6-10 years during dental procedures

Design

A controlled, parallel-group, unblinded, randomized clinical trial on 30 patients. Random allocation software was used for randomization.

Settings and conduct

Children in the case and control groups receive an injection of inferior alveolar nerve block anesthesia for the necessary dental treatment. The treatment is done in the dental clinic of the university from 9 to 12 in the morning. Patients in the case group are placed in a room scented with a warmer containing Neroli essential oil for 10 minutes before receiving anesthesia. Patients in the control group are placed in a room with a warmer containing distilled water for 10 minutes before receiving anesthesia.

Participants/Inclusion and exclusion criteria

6-10 year old children with mild dental anxiety

Intervention groups

Case group: before injection, 6-10 year old healthy children are placed for 10 minutes in a room with a warmer containing Neroli essential oil. Control group: before injection, 6-10 year old healthy children are placed in a room with a warmer containing distilled water for 10 minutes.

Main outcome variables

Child's anxiety during dental treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054428N1**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Registration date

2023-12-30, 1402/10/09

Registrant information

Name

Rojin Soleimanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 2262

Email address

soleymanzade.r@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Neroli essential oil on dental anxiety in children during dental treatment

Public title

The effect of Neroli scent on dental anxiety in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The children should be 6 to 10 years old. The children

need dental treatment with local anesthesia of inferior alveolar nerve block. Mentally and physically healthy children. Group 3 of Frankle classification of children's cooperation in dental treatments.

Exclusion criteria:

Patients have a history of asthma, allergy and sensitivity to citrus. Patients with congenital or acquired abnormalities. Patients suffering from a cold or any disease involving the respiratory system.

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Children were randomly divided into case and control groups by block randomization method. Blocked randomization is for the purpose of making sure that exactly the same number of participants are included in the intervention and control groups at consecutive but equal time intervals, for example, the case group is given to the first block and the control group to the second and again the case group to the third block and so on. Random allocation software is used as randomization tool.

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 Kurdistan University of Medical Sciences

Street address

Faculty of dentistry, Kurdistan university of medical sciences, Pasdaran Ave

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.MUK.REC.1402.187

Health conditions studied

1

Description of health condition studied

Dental anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dental anxiety

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Children's Fear Survey Schedule - Dental Subscale questionnaire, digital sphygmomanometer, pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The child enters a room that has been scented with Neroli essential oil and warmer, and a cotton ball containing a drop of essential oil is placed on her chest, and after 10 minutes, an anesthetic injection is performed.

Category

N/A

2

Description

Control group: The child enters a room where warmer and distilled water have already been placed, then a cotton swab dipped in a drop of water is placed on her/his chest and after 10 minutes, an anesthetic injection is performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan university of medical sciences

Full name of responsible person

Elahe Nazmi

Street address

Kurdistan university of medical sciences, Pasdaran Ave.

City

sanndaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4653

Fax

+98 87 3366 4654

Email

elahe_nazmi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

Kurdistan university of medical sciences, Pasdaran Ave.

City

sanndaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4653

Fax

+98 87 3366 4654

Email

Soleymanzade.R@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Rojin Soleymanzadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Kurdistan university of medical sciences, Pasdaran Ave.

City

sanndaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4653

Email

Soleymanzade.R@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Rojin Soleymanzade

Position

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Person responsible for updating data

Contact

Name of organization / entity

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable