Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the effect of aromatherapy using geranium essential oil compared to water on patients' anxiety during dental procedures in children 6-9 years old

Protocol summary

Study aim
Determining the effect of aromatherapy using geranium on patients' anxiety during dental procedures in children 6 to 9 years old

Design
Cross-over clinical trial with randomized control group phase 2 on 30 patients, randomization was done in a simple way

Settings and conduct
This study is conducted in the dental clinic of Isfahan Faculty of Dentistry, and 15 children are treated in the first session without scent (control) and in the second session with candlestick scent (intervention). 15 other children are treated with scent in the first session (intervention) and without scent (control) in the second session. Children's anxiety is measured and compared using salivary cortisol and heart rate before and after each session.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: Children aged 6 to 9 who need fissure sealant treatment؛ No history of toothache؛ Absence of systemic problems and physical and mental disabilities؛ Has Frankel + and ++ cooperation criteria Exclusion criteria: Patients with the first visit to the dentist؛ Children with a history of allergies and suffering from colds and respiratory diseases and smell disorders؛Patients with spontaneous pain

Intervention groups
15 children are treated in the first session without scent (control) and in the second session with geranium scent (intervention). Another 15 children are treated with scent (intervention) in the first session and without scent (control) in the second session. Children's anxiety is measured and compared using salivary cortisol and heart rate before and after each session

Main outcome variables
Salivary cortisol level, heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220910055931N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **retrospective**

Last update: **2022-09-23, 1401/07/01**
Update count: **0**

Registration date
2022-09-23, 1401/07/01

Registrant information

Name
Homa baninajarian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 386 8194

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-03, 1401/06/12

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of aromatherapy using geranium essential oil compared to water on patients' anxiety during dental procedures in children 6-9 years old

Public title
The effect of aromatherapy with geranium essential oil on children's anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 6 to 9 years who need fissure sealant treatment No history of toothache Absence of systemic problems and physical and mental disabilities It has Frankel + and ++ collaboration criteria

Exclusion criteria:
Patients with the first visit to the dentist Children with a history of allergies and suffering from colds and respiratory diseases and smell disorders Patients with spontaneous pain

Age
From **6 years** old to **9 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **4**
4 saliva samples and 4 heart rate values for each person

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done from among the qualified clients in an easy and random way up to the required sample size to divide the patients into two groups and what intervention should be done for each patient in the first and second sessions in envelopes labeled as two groups. Intervention/Control) It is written that the patients are asked to choose an envelope as they wish and they are placed in one of two groups based on the title inside the envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences

Street address
No. 23, Shahid Motazadi Alley., Azar Ave., mottahari Ave

City
esfahan

Province
Isfehan

Postal code
8133743744

Approval date
2022-08-22, 1401/05/31

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.196

Health conditions studied

1

Description of health condition studied
Anxiety caused by dental treatments

ICD-10 code
F40

ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Salivary cortisol

Timepoint
Measurement of salivary cortisol in the first and second sessions before dental work and re-measurement approximately 15 minutes later.

Method of measurement
Measurement of salivary cortisol with salivary cortisol kit

2

Description
heart rate

Timepoint
Heart rate measurement in the first and second sessions before dental work and re-measurement about 15 minutes later

Method of measurement
Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each child needed two treatments, and all children were treated between 8 and 9 in the morning, and the second visit was done the following week at the same time. In each visit, first the child was separated from his parents by a nurse and transferred to a room. After 5 minutes, a nurse recorded heart rate using a finger-type pulse monitor (Nonin, Chicago, USA) and unstimulated saliva by placing an absorbent cotton ball sublingually (Salivette, Sarstedt Inc. , Newton, NC, Chicago, USA). After 5 minutes, he took it out and put it in a glass tube. Geranium essential oil was used in this research, which was purchased from Gol Sanam Sepid Company. This essential oil contains geraniol with 15.88%, citronellol with 27.2% and linalool with 10.38%.Aromatherapy was performed using an aroma diffuser (operation mode: ultrasonic sound vibration). The tank volume of the device was 150 ml, and in this study, we poured 100 ml of water with 3 drops of essential oil into the tank, then the device spread the fragrance of geranium flowers with a frequency of 50-60 Hz in the air of a room with an area of 10 square meters. All these works were done half an hour before the first patient entered the room. We used the same dental procedure on both occasions, which is a fissure sealant therapy for one of the first permanent molars, which was performed by a senior student of pediatric dentistry. It is done which consists of cleaning the teeth with a handpiece at low speed and a brush with rotating bristles.After completing the treatment, the nurse took a saliva sample and recorded the pulse rate and labeled it as the second sample. . In another visit, dental treatment was performed and samples were taken following the same method, and the third and fourth samples were collected. By collecting four samples from each child, a total of 120 samples were obtained. At the end of each round, the samples were sent to the laboratory.

Category

Treatment - Drugs

2

Description

Control group: Each child needed two treatments, and all children were treated between 8 and 9 am, and the second visit was done the following week at the same time. In each visit, first the child was separated from his parents by a nurse and transferred to a room. After 5 minutes, a nurse recorded heart rate using a finger-type pulse monitor (Nonin, Chicago, USA) and unstimulated saliva by placing an absorbent cotton ball sublingually (Salivette, Sarstedt Inc. , Newton, NC, Chicago, USA). After 5 minutes, it was taken out and placed in a glass tube.Aromatherapy with water was done by an aroma diffuser device (operation mode: ultrasonic sound vibration). The tank volume of the device was 150 ml, and in this study, we poured 100 ml of water into the tank, then the device, with a frequency of 50-60 Hz, spread water vapor in the air of a room with an area of 10 square meters. All these works were done half an hour before the first patient entered the room. We used the same dental procedure on both occasions, which is a fissure sealant therapy for one of the first permanent molars, which was performed by a senior student of pediatric dentistry. It is done which consists of cleaning the teeth with a handpiece at low speed and a brush with rotating bristles.After completing the treatment, the nurse took a saliva sample and recorded the pulse rate and labeled it as the second sample. . In another visit, dental treatment was performed and samples were taken following the same method, and the third and fourth samples were collected. By collecting four samples from each child, a total of 120 samples were obtained. At the end of each round, the samples were sent to the laboratory.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan University of Dentistry

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Isfahan University of Medical Sciences Research Assistant
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
Esfahan University of Medical Sciences
Full name of responsible person
Homa Baninajarian
Position
Assistant professor
Latest degree
Specialist
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data is shared after de-identifying individuals
When the data will become available and for how

long

Access starts 6 months after the publication of the article

To whom data/document is available

Researchers and students

Under which criteria data/document could be used

If people cannot be identified

From where data/document is obtainable

Sofeh Blvd., Isfahan Faculty of Dentistry, Dr. Homa Bani Najarian Email: H. Baninajarian@yahoo.com

What processes are involved for a request to access data/document

For use in future studies

Comments