

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the effect of aromatherapy with lavender essential oil on dental anxiety by measuring pulse rate and salivary cortisol during dental treatment in pediatric patients

Protocol summary

Study aim

This randomized controlled clinical trial is performed to evaluate the effect of aromatherapy with lavender essential oil on salivary cortisol and pulse rate as indicators for child's anxiety during dental treatment.

Design

cross over clinical trial using block randomization, including 24 patients, double blinded

Settings and conduct

This study is performed in the Pediatric Dental Clinic of Shiraz University of Medical Science. 24 children are selected and divided in to two groups due to block randomization. One group in the first visit and an other one in the second visit, receive the composite filling restorative treatment in the room with lavender aroma diffused in the air. For each group the same treatment is done without aroma in the other visit. Pulse rate and visual analog scale (VAS) are recorded and saliva samples (for cortisol level analyzing) are collected during each session, to evaluate the child's anxiety. The children and the nurse who record pulse rate and VAS and collect saliva samples are not aware of the study aim and probable effect of the aroma.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy children with 7-9 years of age, who exhibit Frank's behavior rating grade III or IV and have decayed lower second primary molars bilaterally which need class I restorative treatment. Exclusion Criteria: Patients who have any history of dental pain, previous dental visit, history of allergy, children with common cold and children who currently use any medication.

Intervention groups

12 children receive cl 1 composite filling while lavender aroma is diffused in the air during the first visit, and receive the treatment without aroma during the second visit. Other 12 children receive the restorative treatment

without aroma in the first and with aroma in the second visit.

Main outcome variables

salivary cortisol level, pulse rate and visual analog scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190119042406N1**

Registration date: **2019-02-11, 1397/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-11, 1397/11/22**

Update count: **0**

Registration date

2019-02-11, 1397/11/22

Registrant information

Name

Neda Solhjoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 8096

Email address

solhjoo_neda@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of aromatherapy with lavender essential oil on dental anxiety by measuring pulse rate and salivary cortisol during dental treatment in pediatric patients

Public title

Evaluation of the effect of aromatherapy on dental anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy children with 7-9 years of age Patients who exhibit Frank's behavior rating grade III or IV Children who have decayed lower second primary molars bilaterally which need class I restorative treatment

Exclusion criteria:

Patients who have any previous dental visit Children with common cold Children with history of allergy Children who currently use any medication Patients with any history of dental pain

AgeFrom **7 years** old to **9 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **4**

we collect 2 saliva samples from each patient in each visit. Overall 4 saliva samples will be collected from each patient.

Randomization (investigator's opinion)

Randomized

Randomization description

Block permutation design was used to randomized patients to case and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

pediatric patients and the person who evaluates the consequences and the analyzer won't be aware of the goal of the aromatherapy.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd, Shiraz university of medical sciences.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-11-27, 1397/09/06

Ethics committee reference number

IR.SUMS.REC.1397.839

Health conditions studied**1****Description of health condition studied**

Dental anxiety in pediatric patients

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

Salivary cortisol level

Timepoint

Saliva samples are collected before and after dental treatment.

Method of measurement

The level of cortisol in saliva samples are detected using commercial ELISA cortisol kit.

Secondary outcomes**1****Description**

Pulse rate

Timepoint

Before the treatment, during the treatment after drilling, at the end of the treatment

Method of measurement

Finger type pulse oximeter

2

Description

Patient's anxiety in a subjective way

Timepoint

After injection of local anesthesia

Method of measurement

visual analog scale

Intervention groups

1

Description

Intervention group: Each patient receive restorative treatment under aromatherapy with lavender essential oil in the intervention session. 2 drops of pure lavender essential oil from Tisserand company is poured in 100 ml water in Zyklusmed humidifier and diffused in the air 30 minutes before patient's arrival.

Category

Treatment - Other

2

Description

Control group: Each patient receive restorative treatment without aromatherapy with lavender essential oil in the control session. Only water is poured in Zyklusmed humidifier and water steam diffuse in the air 30 minutes before patient's arrival.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic of Shiraz university of medical sciences

Full name of responsible person

Dr. Mahtab Memarpour

Street address

Qomabad Ave, Ghasredasht Blvd, Shiraz dental school

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dental@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR.Yoones Ghasemi

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Zand Blvd, Central building of Shiraz university of medical sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Neda Solhjoui

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Faezeh Ghaderi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Fax**Email**

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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

After making the participants unknown, all data are accessible .

When the data will become available and for how long

Data will be accessible 6 months after publishing the results.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Data will be accessible to the studies in which these data are needed such as meta analysis.

From where data/document is obtainable

Ghaderi_fa@sums.ac.ir solhjoo_neda@yahoo.com

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

Applicants for data should present the researchers the university authorization.

Comments