Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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, recieve 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 Solhjou
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3632 8096
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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
Age
From **7 years** old to **9 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target 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 esch 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 wont 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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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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713451978
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vcrdep@sums.ac.ir
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 Solhjou
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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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 mete 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