Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of aromatherapy with orange essential oil on children anxiety during dental treatment

Protocol summary

Summary

To evaluate the effect of orange odor on reduction of children anxiety during dental treatment in a randomized study. Among 6 to 9 years old children who need to fissuresealant therapy of at least 2 first permanent molars, 30 cases are selected. Our selection and division in two groups is randomized. This study will be performed in two dental visits for each case. In each visit, first prophylaxy and then fissuresealant therapy will be performed with conventional behavior management (tell, show, do). 15 children will be exposed to orange odor in first visit and will be treated in the second one conventionally. Another15 children will be exposed to orange odor in second visit and will be treated in the first cession conventionally. We use natural essential oil of orange in a diffuser for case group and water for control group. We assess salivary cortisol and heart rate for anxiety evaluation two times (before and after treatment) in each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201258821N1**
Registration date: **2012-03-01, 1390/12/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

Fateme Farahbakhsh pour

Name of organization / entity

Dental faculty, Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research center of dental faculty of Isfahan university of medical sciences

Expected recruitment start date

2012-02-29, 1390/12/10

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with orange essential oil on children anxiety during dental treatment

Public title

Effect of aromatherapy on children anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 6 to 9 years old; need to fissuresealant therapy of at least 2 first permanent molars; absence of dental caries in related teeth; absence of systemic problems and mental and physical disability; absence of defect in olfactory and respiratory system; frankle + in frankle cooperation criteria. Exclusion criteria: history of dental treatment; catch cold; asthma and allergy.

Age

From **6 years** old to **9 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
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
Reasearch center of faculty of dentistry of Isfahan university of medical sciences
Street address
Dental faculty of Isfahan medical sciences, Hezar Jerib avenue
City
Isfahan
Postal code
81846-73461
Approval date
2011-05-28, 1390/03/07
Ethics committee reference number
390146

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F40
ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
anxiety
Timepoint
two times in each visit,before and after intervention
Method of measurement
salivary cortisol and heart rate

Secondary outcomes

1

Description
salivary cortisol
Timepoint
two times in each visit,before and after intervention
Method of measurement
saliva sampling

2

Description
heart rate
Timepoint
two times in each visit,before and after intervention
Method of measurement
pulseoximeter

Intervention groups

1

Description
Intervention group: orange odor, prophylaxy, fissuresealant therapy.
Category
Other

2

Description
Control group: prophylaxy, fissuresealant therapy
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of pediatric dentistry, dental faculty of Isfahan university of medical sciences
Full name of responsible person
Dr fateme Farahbakhsh pour
Street address
Dental faculty of Isfahan university of medical sciences, Hezar Jerib avenue
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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research center of dental faculty of Isfahan university of medical sciences

Full name of responsible person
Dr Mehdi Jaafarzade

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Dental faculty of Isfahan university of medical sciences, Hezar Jerib avenue

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Grant name

Grant code / Reference number
390146

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

Title of funding source
Research center of dental faculty of Isfahan university of medical sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Dental faculty of Isfahan university of medical sciences

Full name of responsible person
Dr Fateme Farahbakhsh pour

Position
postgraduate student of pediatric dentistry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty