

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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. Another 15 children will be exposed to orange odor in second visit and will be treated in the first session 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**

Research center of faculty of dentistry of Isfahan university of medical sciences

Street address

Dental faculty of Isfahan medical sciences, Hezar Jerib avenue

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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

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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

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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