

# 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)

##### Phone

+98 31 1626 8215

##### Email address

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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

**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

**City**

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

**Street address**

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

**City**

Isfahan

**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****Street address**

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8174673461

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### Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Dental faculty of Isfahan university of medical sciences

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**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*