

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of the effect of Persica chewing gum versus sodium fluoride chewing gum on salivary fluoride concentration in 20-30 years old dental students of Isfahan University

#### Protocol summary

##### Summary

Aim: To determine the amounts of fluoride ion release following using persica chewing gum and sodium fluoride chewing gum. Methods: 44, 20-30 year- old subjects will be selected randomly with regard to inclusion criteria: normal salivary flow rate, using no medications, using no systemic / topical fluoride (except tooth paste), excessive tea drinking habit and persica mouthwash users. The subjects will be asked to sign an informed consent. For one week, they will refrain from drinking tea and will use toothpaste with similar fluoride concentration (Running Period). All the participants, the practitioner and Lab technician will be blind during all the steps of the trial about the type of chewing gum used and saliva samples, respectively. This triple blind cross over study will be performed twice with ten-day interval (washout phase). Both types of chewing gum have the same amount of fluoride, color, shape and taste and will be synthesized by one chemist. During both phases of trial, saliva samples will be collected under controlled conditions at similar times in the morning within baseline, 5, 10, 20, 45 min. intervals following 5 min. chewing the gums. After labelling each container with code and date, the samples will be weighted and stored at -18°C until fluoride analysis. Saliva flow rate (ml/min) and mean fluoride concentrations during different periods and using different chewing gums will be compared and results will be disseminated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012091810872N1**

Registration date: **2012-12-26, 1391/10/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-26, 1391/10/06

##### Registrant information

###### Name

Mehrnoosh Babaei

###### Name of organization / entity

Dental College of Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2891

###### Email address

mehrnoosh\_babaei@dnt.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of dental college of Isfahan University of Medical Sciences

##### Expected recruitment start date

2012-11-10, 1391/08/20

##### Expected recruitment end date

2012-11-20, 1391/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Persica chewing gum versus sodium fluoride chewing gum on salivary fluoride concentration in 20-30 years old dental students of Isfahan University

## Public title

Evaluation of fluoride released from persica chewing gum compared to sodium fluoride chewing gum

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: 20-30 year- old dental students who are systematically healthy; good oral hygiene; Normal salivary flow rate; Using no medication; Using no systemic or local fluoride supplements (except tooth paste); Not smoking exclusion criteria: Any report of systemic/oral diseases during studying phases; Excessive tea drinking; Using medication; Using Persica / fluoride mouthwashes; Smoking

## Age

From **20 years** old to **30 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **44**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice chancellor for research of Dental College of Isfahan university of Medical Sciences

##### Street address

Dental College, Isfahan University of Medical Sciences, Azadi square(Darvazeh Shiraz), Isfahan

##### City

Isfahan

##### Postal code

8174673461

## Approval date

2012-11-05, 1391/08/15

## Ethics committee reference number

391307

## Health conditions studied

### 1

#### Description of health condition studied

The mean of saliva fluoride concentration following using persica chewing gum

#### ICD-10 code

Z01.2

#### ICD-10 code description

Dental examination

## Primary outcomes

### 1

#### Description

Salivary Fluoride ion

#### Timepoint

Before intervention, 5, 10, 20, 45 min after intervention

#### Method of measurement

Mean fluoride ion released in terms of ppm and with laboratory analysis

## Secondary outcomes

### 1

#### Description

Stimulated salivary flow rate

#### Timepoint

Before intervention, 5, 10, 20, 45 min after intervention

#### Method of measurement

Mean Stimulated salivary flow rate in terms of ml/min with laboratory analyze

## Intervention groups

### 1

#### Description

Intervention group: chewing Persica, 750 mg gum, once, 5 minutes

#### Category

Prevention

### 2

#### Description

Control group: chewing sodium fluoride, 750 mg gum, once, 5 minutes

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental College of Isfahan University of Medical

Sciences

**Full name of responsible person**

Doctor Shiva Mortazavi-Pediatric Dentist-Assistant professor

**Street address**

Isfahan university, Azadi square(Darvazeh Shiraz), Isfahan

**City**

Isfahan

Isfahan

**Postal code**

8174673461

**Phone**

+998 3117922891

**Fax**

+98 31 1668 7080

**Email**

sh\_mortazavi@dnt.mui.ac.ir

**Web page address**

www.dnt.mui.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Dental College of Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Omid Savabi-Vice chancellor for research chief of Dental College of Isfahan University of Med

**Street address**

Vice chancellor for research, Dental College, Isfahan University, Azadi square, Isfahan

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

391307

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

Yes

**Title of funding source**

Vice chancellor for research of Dental College 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 college of Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Shiva Mortazavi

**Position**

Pediatric Dentist, Assistant Professor

**Other areas of specialty/work**

**Street address**

Dental College, Isfahan University of Medical Sciences, Azadi square(Darvazeh Shiraz), Isfahan

**City**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Dental College of Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Shiva Mortazavi

**Position**

Pediatric Dentist, Assistant Professor

**Other areas of specialty/work**

**Street address**

Dental College, Isfahan University of Medical Sciences, Azadi square(Darvazeh Shiraz), Isfahan

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**Email**

sh\_mortazavi@dnt.mui.ac.ir

**Web page address**

www.dnt.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Dental College of Isfahan University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Babaei

**Position**

General Dentist, Pediatric dentistry Resident

**Other areas of specialty/work**

**Street address**

Dental College, Isfahan University of Medical Sciences, Azadi square(Darvazeh Shiraz), Isfahan

**City**

Isfahan

**Postal code**

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**Phone**

+98 31 1792 2891

**Fax**

+98 31 1668 7080

**Email**  
mehrnoosh\_babaei@dnt.mui.ac.ir  
mdmasiha@yahoo.com  
**Web page address**  
www.dnt.mui.ac.ir

**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*