

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

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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

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Isfahan

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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-Assisstant professor

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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

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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

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Person responsible for updating data

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General Dentist, Pediatric dentistry Resident

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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