

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of chewing gum containing CPP-ACP on salivary concentration of calcium , phosphate and alkaline phosphatase in 7-11 years old children with severe caries

Protocol summary

Summary

aim:Effect of chewing gum containing CPP-ACP on salivary concentration of calcium , phosphate and alkaline phosphatase in 7-11 years old children with severe caries; Inclusion criteria: No caries in the first group, tooth decay at least 6 to Group II; Exclusion criteria: Any report of systemic diseases, History of radiotherapy and chemotherapy,Anticholinergic drugs;The study population: 64 7-11 years old children, sample size:64 ;studied interventions:gum containing CPP-ACP,caries; The main outcome variable:concentration of calcium , phosphate and alkaline phosphatase

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062528624N1**
Registration date: **2016-07-15, 1395/04/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-15, 1395/04/25

Registrant information

Name

Avin Fattahi

Name of organization / entity

Islamic Azad University of Isfahan (Khorasgan), Dental School

Country

Iran (Islamic Republic of)

Phone

+98 31 3535 4053

Email address

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University of Isfahan (Khorasgan)

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-14, 1394/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of chewing gum containing CPP-ACP on salivary concentration of calcium , phosphate and alkaline phosphatase in 7-11 years old children with severe caries

Public title

Effect of chewing gum on saliva materials in children with severe caries

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: No caries in the first group; tooth decay at least 6 to Group II. Exclusion criteria: Any report of systemic diseases; History of radiotherapy and chemotherapy; Anticholinergic drugs; Lack of cooperation during the study; Using medication within 2 hours before sampling

Age

From **89 years** old to **85 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Isfahan (Khorasgan), Dental School

Street address

Islamic Azad University of Isfahan (Khorasgan), Jay Street

City

Isfahan

Postal code

Approval date

2016-05-28, 1395/03/08

Ethics committee reference number

IR.mui.rec.1394.4.23

Health conditions studied

1

Description of health condition studied

salivary concentration of calcium , phosphate and alkaline phosphatase

ICD-10 code

Z01.2

ICD-10 code description

Dental examination

Primary outcomes

1

Description

calcium

Timepoint

5 and 20 minutes after chewing gum

Method of measurement

with laboratory analysis

2

Description

phosphate

Timepoint

5 and 20 minutes after chewing gum

Method of measurement

with laboratory analysis

3

Description

alkaline phosphatase

Timepoint

5 and 20 minutes after chewing gum

Method of measurement

with laboratory analysis

Secondary outcomes

1

Description

calcium

Timepoint

5 and 20 minutes after chewing gum

Method of measurement

with laboratory analysis

Intervention groups

1

Description

Intervention: trident gum, 20 minutes of chewing,Sampling 5 minutes after chewing gum

Category

Diagnosis

2

Description

Control: Intervention: trident gum, 20 minutes of chewing,Sampling 5 minutes after chewing gum

Category

Diagnosis

3

Description

Intervention: trident gum, 20 minutes of chewing,Sampling 20 minutes after chewing gum

Category

Diagnosis

4

Description

control: trident gum, 20 minutes of chewing,Sampling 20 minutes after chewing gum

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Isfahan (Khorasgan), Dental School

Full name of responsible person

Avin Fattahi

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Islamic Azad University Isfahan (Khorasgan)

Full name of responsible person

dr Vahid Esfahanian

Street address

Islamic Azad University of Isfahan (Khorasgan), Dental School

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Islamic Azad University Isfahan (Khorasgan)

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

Islamic Azad University of Isfahan (Khorasgan), Dental School

Full name of responsible person

Avin Fattahi

Position

Pediatric Dentistry/phd

Other areas of specialty/work

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Web page address

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