

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A Comparison Study of Effect of Casein Phosphopeptide Amorphous Calcium Phosphate and Fluoride Varnish on Dentinal Hypersensitivity

Protocol summary

Summary

Aim of the study: The aim of this study was to compare the effect of casein phosphopeptide amorphous calcium phosphate paste and fluoride varnish on dentin hypersensitivity. Studied population: Inclusion criteria: patient with at least two sensitive teeth in each quadrant; teeth with at least 2mm dentin loss; Exclusion: caries; erosion; attrition; cracked tooth; restored tooth. Studied population: patients referred to operative and periodontics departments of Khorasghan dental school which complained of dentin hypersensitivity in age between 20 – 50 years were examined. Sample Size: three groups with 10 patients (totally 30 patients). Study design: In this clinical trial study with parallel design the patients were examined in three groups as followed: in two groups patients treated with Fluoride varnish and casein phosphopeptide amorphous calcium phosphate according to manufacturer instruction. No treatment was done in control group. Dentin hypersensitivity measured at the baseline and one week, two weeks, four weeks and eight weeks after treatment. Visual analog score used for dentin hypersensitivity measurement. Studied intervention and time: fluoride varnish and casein phosphopeptide amorphous calcium phosphate were used three times in a month. Primary outcome: decreased dentin hypersensitivity following using two agents was observed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202149008N1**
Registration date: **2013-11-08, 1392/08/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-08, 1392/08/17

Registrant information

Name

Leila Pischevar

Name of organization / entity

Islamic Azad University (Khorasghan branch)

Country

Iran (Islamic Republic of)

Phone

+98 31 1535 4053

Email address

l.pischevar@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad university, Khorasghan branch (Esfahan),
Dental school

Expected recruitment start date

2011-10-10, 1390/07/18

Expected recruitment end date

2012-10-10, 1391/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison Study of Effect of Casein Phosphopeptide Amorphous Calcium Phosphate and Fluoride Varnish on Dentinal Hypersensitivity

Public title

A comparison study between the effect of two desensitizing agents on dental hypersensitivity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with at least two sensitive tooth in each quadrants; at least 2 mm dentin loss
Exclusion criteria: teeth require any restorative regimen; teeth with erosion; teeth with attrition; teeth with caries; cracked teeth; teeth with restoration; pulpitis

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not 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 khorasgan branch(Esfahan)
dental school

Street address

Arghavanieh, Blv Danrshgah, Islamic Azad university
khorasghan bransh, Esfahan

City

Esfahan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

23810201892047

2

Ethics committee

Name of ethics committee

Islamic Azad University, Khorasgan branch

Street address

Arghavanieh, Blv Danesshgah, Islamic Azad university
, Khorasgan branch

City

Esfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

23810201892047

Health conditions studied

1

Description of health condition studied

dentinal hypersensitivity

ICD-10 code

k03.8

ICD-10 code description

Sensitive dentine

Primary outcomes

1

Description

dentinal hypersensitivity

Timepoint

before intervention, 1week, 4 weeks, 8 weeks after
intervention

Method of measurement

visual analog scale

Secondary outcomes

1

Description

dentinal hypersensitivity

Timepoint

dentinal hypersensitivity

Method of measurement

visual analog scale

Intervention groups

1

Description

Intervention group 1: Fluoride varnish dosage: 3 minutes
3 times

Category

Treatment - Drugs

2

Description

Intervention group 2: casein phosphopeptide paste,
dosage: 3 minutes 3 times

Category

Treatment - Drugs

3

Description

control group: without intervention

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Islamic Azad university

Full name of responsible person

Leila Pischevar

Street address

Arghavanieh, Blv Daneshgah, Islamic Azad university,
Khorasgan branch, Esfahan

City

Esfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Vice- Chancellor of Islamic Azad University
Khorasgan Branch

Full name of responsible person

Esfahanian Vahid

Street address

Arghavanieh, BLV daneshgah, Islamic Azad
University, Esfahan

City

Esfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Vice- Chancellor of Islamic Azad University
Khorasgan Branch

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, khorasgan branch

Full name of responsible person

Leila Pischevar

Position

MSc, assistant professor

Other areas of specialty/work**Street address**

Arghavanieh, BLV Daneshgah, Islamic Azad
university, Khorasgan branch, Esfahan

City

Esfahan

Postal code**Phone**

+98 31 1535 4053

Fax**Email**

lpischevar@hotmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad university, Khorasgan branch

Full name of responsible person

Leila Pischevar

Position

MSc/ assistant professor

Other areas of specialty/work**Street address**

Arghavanieh, BLV Daneshgah, Islamic Azad university
Khorasgan branch, Esfahan

City

Esfahan

Postal code**Phone**

+98 31 1535 4053

Fax**Email**

lpischevar@hotmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad university, Khorasgan branch

Full name of responsible person

Leila Pischevar

Position

MSc/ assistant professor

Other areas of specialty/work**Street address**

Arghavanieh, BLV Daneshgah, Islamic Azad university
Khorasgan branch, Esfahan

City

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Postal code**Phone**

+98 31 1535 4053

Fax**Email**

lpischevar@hotmail.com | lpischevar@khuisf.ac.ir

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