

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of systemic capsaicin on the prevention of tooth sensitivity after in-office bleaching

Protocol summary

Summary

Aim of study: determine and compare the mean of tooth sensitivity after in-office bleaching with capsaicin and placebo at different times Study design : randomized, single blind, control with placebo, crossover methods and materials : a) study population inclusion criteria: have 6 anterior maxillae teeth without restoration on labial surface exclusion criteria: pregnant or lactating , tooth sensitivity history, expose dentine into oral cavity each group sample size:30 total sample size:60 b) intervention: participants received placebo before bleaching and mark their sensitivity in VAS forms. 2 weeks after they received capsaicin 0/25% before bleaching. c) intervention time: both group received placebo and drug 1 hour before treatment and two other capsules were administered every 8 hours during 24 hours. d) primary outcome: tooth sensitivity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122825729N1**

Registration date: **2016-07-30, 1395/05/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

Maryam Montazeri Shahtouri

Name of organization / entity

dentistry school

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2836

Email address

samimi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

done with personal expense

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of systemic capsaicin on the prevention of tooth sensitivity after in-office bleaching

Public title

Drug effect on tooth sensitivity after bleaching

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) at least 18 yrs old 2) good oral hygiene 3) 6 anterior maxillary teeth without restorations on labial surface 4) exist all 6 anterior maxillary teeth 5) no smoking 6) no recession 7) central incisor with A3 or lighter according (Vita shade guide, Vita Zahnfabrik ,Bad Sackingen, Germany) Exclusion criteria : 1) who have a history of any medical diseases that may interfere with the study 2) smoking in the past 30 days 3) have oral lesion 4) pregnant or lactating women 5) calculus or sever tooth discoloration 6) tooth sensitivity 7) expose dentine into oral cavity 8) who use desensitizer products 9) having sever tooth sensitivity after bleaching

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research chancellery of Isfahan university of medical sciences

Street address

Hezar jerib St, Isfahan university of medical sciences

City

Isfahan

Postal code

Approval date

2016-06-06, 1395/03/17

Ethics committee reference number

ir.mui.rec.1395.3.193

Health conditions studied

1

Description of health condition studied

tooth discoloration

ICD-10 code

K03.6

ICD-10 code description

staining,tooth,teeth (hard tissues) (extrinsic)

Primary outcomes

1

Description

tooth sensitivity

Timepoint

1 h before operation and taking capsules,just after operation,1h and 24h after operation

Method of measurement

VAS form

Secondary outcomes

empty

Intervention groups

1

Description

(Control group:placebo,taking similar to intervention group, every 8 hours (three times a day).

Category

Placebo

2

Description

Intervention group:Capsaicin,capsule 0/25%(50 mg),oral,take every 8 hours (three times a day).(capsules made in Isfahan pharmacology school and capsaicin powder is taken from Amin Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental School

Full name of responsible person

Maryam Montazeri Shahtouri, Post-graduate student of operative dentistry

Street address

Operative dentistry section of Isfahan Dental School

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

personal fund

Full name of responsible person

Maryam Montazeri Shahtouri

Street address

Operative dentistry section,Isfahan 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

personal fund

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**

Isfahan Dental School

Full name of responsible person

Maryam Montazeri Shahtouri

Position

Post-graduate student of operative dentistry

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

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

school of dentistry

Full name of responsible person

pouran samimi dehkordi

Position

associated proffessor

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Isfahan dental school

Full name of responsible person

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Position

post graduate student of operative dentistry

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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