

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Assessment the effect of the amino acid L-arginine / calcium carbonate based bleaching and in-office tooth sensitivity in teeth whitening methods

Protocol summary

Summary

Assessment the effect of the amino acid L-arginine / calcium carbonate based bleaching and tooth sensitivity in teeth whitening procedures in the office: Triple blind random clinical trial inclusion criteria: Inclusion criteria for the study: patients in need of bleaching for which this therapy is indicated This means that teeth whitening treatment that is required for them to be free of caries or restorations have previously done. Ymbaran no complaints from tooth sensitivity in touch and to thermal stimuli Exclusion criteria: patients with a history of disease or are taking medicine for a long time, Women who are breastfeeding and pregnancy, patients with conditions such as exposed dentine hypersensitivity and cervical lesions of non-carious teeth Intervention: Use toothpaste containing amino acid L-arginine / calcium carbonate, during and after treatment in-office teeth whitening. The intervening period: 8 months The main outcomes measured: the amount of tooth sensitivity reported by patients before, during, immediately after treatment, and one month after in-office bleaching of vital teeth and bleaching the bleaching agents or other consequences as underlying confounding should be measured: Disorder of tooth sensitivity in understanding the right half or left central incisor to solve the problem, situated between the center line position is not evaluated. Error in evaluation by spectrophotometer color due to surface curvature canine teeth are not evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011832043N1**
Registration date: **2017-05-30, 1396/03/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Elham Ahsani

Name of organization / entity

School of Dentistry, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3893 4528

Email address

ahsanie901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, School of Dental Research Council. Governmental

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-03-04, 1395/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of the amino acid L-arginine / calcium carbonate based bleaching and in-office tooth sensitivity in teeth whitening methods

Public title

Assessment the effect of the amino acid L-arginine / calcium carbonate based bleaching and in-office tooth sensitivity in teeth whitening methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients in need of bleaching for which this therapy is indicated This means that teeth whitening treatment that is required for them to be free of caries or restorations have previously done; Patient aged 18 to 40 years; Patients in good general health and oral; No patients complained of tooth sensitivity in touch and to thermal stimuli. Exclusion criteria: patients with a history of disease or are taking medicine for a long time; People who use orthodontic appliance; patients who have periodontal disease or poor oral hygiene; Women who are breastfeeding and pregnancy; patients with conditions such as exposed dentine hypersensitivity and cervical lesions of non-cariou teeth; People who in the past three months have a history of allergy treatments.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Opposite to Mellat Park, Vakil Abad Blvd

City

Mashhad

Postal code

Approval date

2017-01-22, 1395/11/03

Ethics committee reference number

IR.mums.sd.REC.1394.190

Health conditions studied

1

Description of health condition studied

Change the color of dental unpleasant

ICD-10 code

K03.6

ICD-10 code description

Staining of teeth: NOS extrinsic NOS

Primary outcomes

1

Description

The tooth sensitivity

Timepoint

Before treatment, immediately after completion of the work, 24 hours after treatment and one month later

Method of measurement

The patient is sensitive to cold stimuli by benchmark VImS and spontaneous sensitivity VAS

Secondary outcomes

1

Description

Improved speed color change

Timepoint

Before treatment, immediately after treatment and 24 hours later and one month later

Method of measurement

By photography and visual assessment and spectrophotometry

2

Description

The amount of color change

Timepoint

Before treatment, immediately after treatment and 24 hours later and one month later

Method of measurement

By photography and visual assessment and spectrophotometry

Intervention groups

1

Description

Tooth bleaching gel composition in the experimental group at the office with a paste containing amino acid L-arginine and calcium carbonate will be used during teeth whitening treatment.

Category

Treatment - Drugs

2

Description

In the control group whitening gels alone will be used.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Elham Ahsani

Street address

Opposite to Mellat Park, Vakil Abad Blvd.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice
President of Research

Full name of responsible person

Hamide Sadat Mohammadipour

Street address

Opposite to Mellat Park, Vakil Abad Blvd.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences, Vice President of
Research

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

Mashhad University of Medical Sciences

Full name of responsible person

Hamide Sadat Mohammadipour

Position

Assistant Professor of Restorative Dentistry

Other areas of specialty/work

Street address

Opposite to Mellat Park, Vakil Abad Blvd.

City

Mashhad

Postal code

9177948959

Phone

+98 51 3883 2300

Fax

Email

Mohammadipourh@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamide Sadat Mohammadipour

Position

Specialist of Operative Dentistry

Other areas of specialty/work

Street address

Opposite to Mellat Park, Vakil Abad Blvd.

City

Mashhad

Postal code

9177948959

Phone

+98 51 3883 2300

Fax

+98 51 3882 9500

Email

Mohammadipourh@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elham Ahsani

Position

PhD student of dentistry

Other areas of specialty/work

Street address

Opposite to Mellat Park, Vakil Abad Blvd.

City

Mashhad

Postal code

9177948959

Phone

+98 51 3883 2300

Fax

+98 51 3882 9500

Email

ahsanie901@mums.ac.ir; elhamahsani@yahoo.com

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