Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of dental bleaching with carbamide peroxide 15% and carbamide peroxide 20% on periodontal health

Protocol summary

Study aim

Comparison of the effect of dental bleaching with carbamide peroxide 15% and carbamide peroxide 20% on periodontal health

Design

A randomized single-blinded clinical trial with parallel groups including two intervention groups and one control group.

Settings and conduct

Dental bleaching may damage periodontal tissues. This single-blinded clinical trial was conducted at a private office in Ahvaz. 45 volunteers were divided to three groups (n=15) according to bleaching agent: Intervention group 1 (carbamide peroxide 15%), Intervention group 2 (carbamide peroxide 20%), and control group (placebo). After administration of the agents for 8 hours/night for 6 nights, plaque index, gingival index and bleeding on probing were evaluated at four time points (baseline, 7th, 14th and 21th day after dental bleaching).

Participants/Inclusion and exclusion criteria

Inclusion criteria: need for dental bleaching, general health, aged 20 to 40 years, having at least 12 teeth from 3 to 14, agree to participate and fulfill the study phase; Exclusion criteria: oral diseases, systemic diseases, Allergic to dental bleaching agents, the presence of crown and extensive composite restoration in the teeth receiving dental bleaching.

Intervention groups

Intervention group 1: dental bleaching with carbamide peroxide 15% (Ultradent, USA) for 8 hours) 8 hours/night for 6 nights. Intervention group 2: dental bleaching with carbamide peroxide 20% (Ultradent, USA) 8 hours/night for 6 nights, Control group: Using anti-allergic gel (Ultradent, USA) as placebo 8 hours/night for 6 nights

Main outcome variables

Plaque index (PI), gingival index (GI) and bleeding on probing (BOP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190509043541N2**
Registration date: **2019-06-30, 1398/04/09**
Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**
Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name
Azarnoush Aryankia
Name of organization / entity
Country
Iran (Islamic Republic of)
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aryankian-a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2019-03-03, 1397/12/12

Actual recruitment start date

2018-04-09, 1397/01/20

Actual recruitment end date

2019-03-03, 1397/12/12

Trial completion date

2019-04-09, 1398/01/20

Scientific title

Comparison of the effect of dental bleaching with carbamide peroxide 15% and carbamide peroxide 20% on periodontal health

Public title
Effect of dental bleaching on periodontal health
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Need to bleach teeth General health Aged 20 to 40 years Having at least 12 teeth from 3 to 14 Agree to participate and fulfill the study phase
Exclusion criteria:
Oral diseases Systemic diseases Allergy to bleaching agents The presence of crown and extensive composite restoration in the teeth receiving dental bleaching
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Using random number table including numbers 1-45: numbers 1-15, 16-30 and 31-45 were assigned for intervention group 1 (carbamide peroxide 15%), intervention group 2 (carbamide peroxide 20%) and control group (placebo), respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcomes evaluator was kept blind to the type of substances used as bleaching agent or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
5618985991
Approval date
2018-06-10, 1397/03/20
Ethics committee reference number
IR.AJUMS.REC.1397.960

Health conditions studied

1

Description of health condition studied
Periodontal health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plaque index
Timepoint
At the beginning of the study (before the intervention), and days 7, 9 and 21 after intervention fulfillment
Method of measurement
Clinical by Loe and Silness plaque index

2

Description
Gingival index
Timepoint
At the beginning of the study (before the intervention), and days 7, 9 and 21 after intervention fulfillment
Method of measurement
Clinical by Loe and Silness gingival index

3

Description
Bleeding on probing
Timepoint
At the beginning of the study (before the intervention), and days 7, 9 and 21 after intervention fulfillment
Method of measurement
Periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: dental bleaching with carbamide peroxide 15% (Ultradent, USA) for 8 hours/night for 6 nights

Category

Treatment - Other

2

Description

Intervention group 2: dental bleaching with carbamide peroxide 20% (Ultradent, USA) for 8 hours/night for 6 nights

Category

Treatment - Other

3

Description

Control group: Using anti-allergic gel (Ultradent, USA) as placebo 8 hours/night for 6 nights

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Azadeh Ghaemi dental office

Full name of responsible person

Dr. Azadeh Ghaemi

Street address

No.6, Farabi, 5 West Ave., Kianpars

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6155884654

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

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Grant name

Ahvaz University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Azarnoush Aryankia

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available