

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Influence of whitening and regular dentifrices on color stability of orthodontic clear ligatures in oral environment

Protocol summary

Study aim

Comparison of influence of whitening and regular dentifrices on color stability of orthodontic clear ligatures in oral environment

Design

A randomized, double-blind, randomized controlled clinical trial was performed on 66 patients using the randomization tables available at www.stattrek.com.

Settings and conduct

Patients who are undergoing fixed orthodontic treatment at Ahwaz Dental School are selected at the end of the teeth alignment phase. After obtaining informed consent, Orthogonizers brand ligatures are used on the lower anterior teeth of all patients. Patients are randomly divided into three groups of 22 patients. Patients are asked to brush their teeth twice a day for 5 minutes each time using the toothpaste. Canon cameras are used to determine the primary color. All photos are taken in the same environment and light. It is then placed in the mouth for 4 weeks and the patient brushes the ligatures using the appropriate toothpaste and is removed after this period. Then the samples are photographed again and all the photos (Both primary and post-oral photographs) are examined to determine the color of the ligatures using Photoshop 2019 software to evaluate the L, a, and b parameters.

Participants/Inclusion and exclusion criteria

The patient is willing to participate in the study, Have a good level of oral health, 4 lower anterior teeth are aligned and without diastema, Do not use any mouthwash, medication, tobacco or special diet, Absence of systemic diseases : Patient non-cooperation

Intervention groups

The first group uses Arm & Hammer Advance White Extreme toothpaste, the second group uses Crest Complete Extra Whitening toothpaste and the third group uses regular Crest Cavity Protection toothpaste.

Main outcome variables

The effectiveness of Arm & Hammer Advance White,

Crest Complete Extra Whitening and Crest Cavity Protection toothpaste on color stability of the elastic ligature

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054292N1**

Registration date: **2022-03-28, 1401/01/08**

Registration timing: **prospective**

Last update: **2022-03-28, 1401/01/08**

Update count: **0**

Registration date

2022-03-28, 1401/01/08

Registrant information

Name

Majid Aryannejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3376 5825

Email address

aryannejad.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Influence of whitening and regular dentifrices on color stability of orthodontic clear ligatures in oral environment

Public title
Influence of whitening and regular dentifrices on color stability of orthodontic clear ligatures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient is willing to participate in the study Have a good level of oral health 4 lower anterior teeth are aligned and without diastema Do not use any mouthwash, medication, tobacco or special diet Absence of systemic diseases
Exclusion criteria:
 Patient non-cooperation

Age
From **15 years** old to **25 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random tables available at www.stattrek.com, they are selected by simple individual randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Using tubes that do not have the specifications of the relevant toothpaste on them and the tubes are named by the researcher.

Placebo
Not 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
 Ground Floor, Ahvaz Jundishapur University of Medical Sciences and Health Services, Vice Chancellor for Research and Technology, University City, Ahvaz
City
 Ahvaz
Province
 Khouzestan
Postal code
 1579461357
Approval date
 2022-03-12, 1400/12/21
Ethics committee reference number
 IR.AJUMS.REC.1400.698

Health conditions studied

1

Description of health condition studied
 Influence of whitening and regular dentifrices on color stability of orthodontic clear ligatures
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 The amount of discoloration of clear orthodontic ligatures
Timepoint
 Record the primary color of the ligatures , 28
Method of measurement
 The samples are photographed and all photos (both initial and post-oral photos) to determine the color of the ligatures using Photoshop software version 4. 0. 20 (Adobe Photo Shop cc 2019) for evaluation Parameters L, a, b are checked.

Secondary outcomes

empty

Intervention groups

1

Description
 first Intervention group: Arm & Hammer Advance White Extreme Whitening Toothpaste , Second Intervention group: Crest Complete Extra Whitening toothpaste
Category
 Diagnosis

2

Description

Control group: Crest Toothpaste Cavity Protection
Regular

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur Dental School

Full name of responsible person

Marzieh mazhari

Street address

Jundishapur Dental School, Dey Ave, Golestan Blvd,
Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715775

Phone

+98 61 3360 7544

Email

Marzie.mazhari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Mazhari

Street address

Dental School, Ahvaz Jundishapur University Of
Medical Sciences, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715775

Phone

+98 61 3320 5168

Email

Marzie.mazhari@yahoo.com

Grant name

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

Majid Aryannejad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Jundishapur Dental School, West Dey Ave, Golestan
Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715775

Phone

+98 61 3376 5825

Fax

Email

aryannejad.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Mazhari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthodontics

Street address

Dental school, Ahvaz Jundishapur University Of
Medical Sciences, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715775

Phone

+98 61 3360 7544

Email

Marzie.mazhari@yahoo.com

Fax

Email

aryannejad.m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Aryannejad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Jundishapur Dental School, West Dey Ave, Golestan
Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

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Phone

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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