Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to compare the effectiveness of ordinary toothpaste with fluorescein toothpaste on plaque control in fixed orthodontic patients

Protocol summary

Study aim

To compare the effectiveness of ordinary toothpaste with fluorescein toothpaste on plaque control in fixed orthodontic patients

Design

Totally, 40 patients whose undergoing fixed orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple sampling methods.

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 12 years; physical health conditions; no having tooth decay; no having soft tissue diseases; having fixed orthodontic appliances in both the upper and lower jaws. Exclusion criteria: Having food coloring allergies; using antibiotics for two weeks before.

Intervention groups

The intervention group will receive ordinary toothpaste for a month and then fluorescein toothpaste as well as ultraviolet light device. The patients were requested to identify the spots of the remaining plaques with LED light in a semi-dark room after each brushing and clean them again with a toothbrush in two months. The control group will receive ordinary toothpaste for 2 months.

Main outcome variables

Evaluation and comparison of the orthodontic plaque index and bleeding point index one and two months after intervention in control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047355N1**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **prospective**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date

2020-05-30, 1399/03/10

Registrant information

Name

Masume Charbgoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4722 2195

Email address

charbgoum941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of ordinary toothpaste with fluorescein toothpaste on plaque control in fixed orthodontic patients

Public title
The effectiveness fluorescein toothpaste on plaque control in fixed orthodontic patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
At least 12 years Physical health conditions No having tooth decay No having soft tissue diseases Having fixed orthodontic appliances in both the upper and lower jaws
Exclusion criteria:
Having food coloring allergies Using antibiotics for two weeks before
Age
From **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The subjects will be randomly assigned into three groups of 20 patients with blocks of 2 and 4 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned into the intervention and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2020-04-27, 1399/02/08
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1399.001

Health conditions studied

1

Description of health condition studied
Orthodontic
ICD-10 code
Z46.4
ICD-10 code description
Fitting and adjustment of orthodontic device

Primary outcomes

1

Description
Orthodontic plaque index
Timepoint
One and two months after intervention
Method of measurement
Staining the teeth or surfaces with a plaque-disclosing solution such as erythrosine

2

Description
Bleeding point index
Timepoint
One and two months after intervention
Method of measurement
During the examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive ordinary toothpaste for a month and then fluorescein toothpaste as well as ultraviolet light device. The patients were requested to identify the spots of the remaining plaques with LED light in a semi-dark room after each brushing and clean them again with a toothbrush in two months.

Category

Prevention

2

Description

Control group: The control group will receive ordinary toothpaste for 2 months.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Masume Charbgoo

Street address

Dental Clinic of Mashhad Faculty of Dentistry, Opposite Mellat Park, Vakilabad Blvd

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charbgouM941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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vcresearch@mums.ac.ir

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Masume Charbgoo

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcome or the like can be shared.
When the data will become available and for how long
6 months after printing results
To whom data/document is available
Our data will only be available to researchers working at science centers and universities.
Under which criteria data/document could be used
Our data will be available for scholars working at science centers and universities.
From where data/document is obtainable
Masume Charbgoo provides the data analysis to the applicants via email: charbgouM941@mums.ac.ir
What processes are involved for a request to access data/document
Applicants can respond to the email of the respondent and receive a response within a week.
Comments