

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of Orthokin mouthwash in comparison with chlorhexidine mouthwash on tooth staining in patient with fix orthodontic appliance: A randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of Orthokin and chlorhexidine mouthwash on tooth staining in fixed orthodontic patients.

Design

Randomized clinical trial with control group, parallel design and double blinded.

Settings and conduct

Patients are randomized in two groups. Participants are asked to consume Orthokin (intervention group) and chlorhexidine (control group) mouthwash. Identical toothpastes will be given to both groups. Participants of the groups will be matched according to frequency of consuming staining food (assessed by questionnaire). Randomization will be done by choosing an opaque pockets. Mouthwashes are in identical bottles and the patients and outcome assessor are unaware of the bottle content.

Participants/Inclusion and exclusion criteria

Systematically healthy people with acceptable compliance with orthodontic treatment, who have healthy periodontium. Patients who consume special drugs, have active dental caries or staining or drink tea, coffee or chocolate milk more that three times per day will be excluded.

Intervention groups

Mouth rinse with 15 milliliter of Orthokin mouthwash for 1 minute, three times per day for 4 weeks Mouth rinse with 15 milliliter of chlorhexidine mouthwash for 1 minute, three times per day for 4 weeks

Main outcome variables

Staining status according to Extrinsic Enamel Stain Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020523N4**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Sepideh Soheilifar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

sepidehsoheilifar@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Orthokin mouthwash in

comparison with chlorhexidine mouthwash on tooth staining in patient with fix orthodontic appliance: A randomized clinical trial

Public title

Evaluation of the staining effect of Orthokin mouthwash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systematically healthy people History of acceptable compliance with treatment Healthy periodontium or mild gingivitis with pocket depth less than 3 milimeters and with no loss of attachment

Exclusion criteria:

Special drug consumption (hypertension, antihistamine, chemotherapy drugs) Presence of active dental caries Presence of staining on labial surface of the teeth Consumption of tea, coffee or chocolate milk more than three times per day Smoking

Age

From **14 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was done with individual unit of randomization. Patient allocation and allocation concealment was conducted with numbers in sealed and opaque pockets.

Blinding (investigator's opinion)

Double blinded

Blinding description

Mouthwashes are given in identical bottles and patients are not aware which bottle contains which solution. In addition, the person who assess the staining status and statistician are unaware of the consumed mouthwash.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethnic committee of Hamadan University of Medical Sciences

Street address

Orthodontic department, Dental Faculty, Shahid Fahmideh Street

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Postal code

654178-38741

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.UMSHA.REC.1398.612

Health conditions studied

1

Description of health condition studied

Staining status of teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Staining status according to Extrinsic Enamel Stain Index

Timepoint

At baseline (before intervention) and 4 weeks later

Method of measurement

Extrinsic Enamel Stain Index by Loben method

Secondary outcomes

1

Description

Gingival health status

Timepoint

At baseline and 4 weeks later

Method of measurement

Gingival index

Intervention groups

1

Description

Intervention group: Mouth rinse with 15 milliliter of Orthokin mouthwash (Kin laboratory, Spain) containing diluted chlorhexidine, sodium fluoride and zinc acetate, 1 minute, 3 times per day for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Mouth rinse with 15 milliliter of 2% chlorhexidine mouthwash (Najoo, Iran) , 1 minute, 3 times per day for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Hamadan University of Medical Sciences

Full name of responsible person

Hanane Khodadadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Said Bashirian

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Hananeh Khodadadi

Position

دانشجوی دندانپزشکی

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sepideh Soheilifar

Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data regarding primary outcome measure will be shared.

When the data will become available and for how long

Data will be shared 6 months after data publication

To whom data/document is available

Data will be available for all people.

Under which criteria data/document could be used

Data will be available for future research project and for data accumulation for systematic reviews.

From where data/document is obtainable

Applicant can receive data by sending an email to se.soheilifar@gmail.com.

What processes are involved for a request to access data/document

Applicants can send an email and tell their reason for receiving data. Data will be send within 2 weeks.

Comments