Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
+98 21 2264 2508

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
City
Hamadan
Province
Hamadan
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 floride 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
Street address
Orthodontic department, Dental Fculty, Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
654178-38741
Phone
+98 81 3838 1059
Email
hannaneh_khodadadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Said Bashirian
Street address
Medical Faculty, Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
65178-38736
Phone
+98 81 3838 0717
Email
s_bashirian@yahoo.com
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
Street address
Dental Faculty, Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
654178-38741
Phone
+98 81 3838 1085
Email
hannaneh_khodadadi@yahoo.com

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
Other areas of specialty/work
Dentistry
Street address
Orthodontic department, Dental Faculty, Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan

Postal code
654178-38741
Phone
+98 81 3838 1085
Email
se.soheilifar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Sepideh Soheilifar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmide street, Hamedan University of Medical Sciences, Dental Faculty
City
Hamedan
Province
Hamadan
Postal code
654178-38741
Phone
+98 81 3838 1085
Fax
Email
se.soheilifar@gmail.com
Web page address

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