Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of different methods of fluoride agents prescription on the Surface roughness of Rhodium coated NiTi orthodontic wires

Protocol summary

Study aim
Evaluation of the Effect of different methods of fluoride agents prescription on the load-deflection characteristics of Rhodium-Coated NiTi orthodontic wires.

Design
A non-randomized, single-blind, control group, parallel group clinical trial

Settings and conduct
This study has been conducted on patients referred to Babol Dental School to evaluate the effect of fluoride anticaries agent on a type of orthodontic wire. To do so, the wires are placed in the mouth of the patients, and how to use fluoride is separately explained for each group. After 6 weeks, the wires will be evaluated using Atomic force microscopy. This double-blind study is blinded for both patients and statistical analyzer.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient who has the ability to maintain proper oral hygiene. A patient who has all the maxillary teeth. Exclusion criteria: Patients who do not have the ability to maintain proper oral hygiene. Patients using certain mouthwashes. Patients who have a specific disease affecting the salivary flow (such as Sjogren, etc.). Patients using drugs that have an effect on the salivary flow. Patients who smoke or drink alcohol. Patients who have open-bite. Patients who have long face. Patients who have high levels of acidic food intake in their diet. Patients who have severe crowding in the flat part of the orthodontic wire.

Intervention groups
Control group: Patients who only use fluoride toothpaste. Intervention group 1: Patients who use fluoride toothpaste with daily fluoridated mouthwash Intervention group 2: Patients who use fluoride toothpaste with fluoride gel.

Main outcome variables
Arithmetic mean height (Sa); root mean square height (Sq); maximum height (Sz); root mean square gradient (Sdq); developed interfacial area ratio (Sdr)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180102038190N1**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-12, 1397/12/21**
Update count: **0**

Registration date
2019-03-12, 1397/12/21

Registrant information

Name
Sedigheh Sheikhzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-01, 1397/12/10

Expected recruitment end date
2019-03-16, 1397/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of different methods of fluoride agents prescription on the Surface roughness of Rhodium coated NiTi orthodontic wires

Public title
Effect of fluoride on orthodontic wire
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are able to afford adequate health care Patients who have all of the maxillary teeth Patients between 15-25 years old
Exclusion criteria:
Patients who are not able to afford adequate health care Patients using certain mouthwashes Patients who have a specific disease affecting the flow of saliva (such as Ŝjogren's syndrome, etc.) Patients who use a drug that has an effect on the flow of saliva smokers and alcohol drinkers patients who have dental openbite patients who are longface. patients who have high acid intake in their diet. patients who have excessive crowding on the straight part of wire
Age
From **15 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
the data analyst does not know the type of substance received by the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Ganjafrooz Ave., Babol University of Medical Sciences
City
Babol
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Mazandaran
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Approval date
2017-02-05, 1395/11/17
Ethics committee reference number
MUBABOL.REC.1395.224

Health conditions studied

1

Description of health condition studied
Effect of fluoride on orthodontic wires
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
measured values on "Atomic force microscopy"
Timepoint
Evaluating wires by Atomic force microscopy at the beginning of the study (before intervention) and 6 weeks after placement in the mouth
Method of measurement
Evaluating surface by Atomic force microscopy

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Use of fluoride toothpaste (Oral-B 315 ppm) twice daily
Category
Diagnosis

2

Description
Intervention group: Use Oral-B fluoride toothpaste twice a day with 0.05% fluoride and use daily mouthwash (Oral-B 226 ppm)once a day (15 ml) after brushing for 30 seconds. eating and drinking for 30 minutes after use is prohibited.
Category
Diagnosis

3

Description
Intervention group: Use Oral-B fluoride toothpaste twice

a day with 0.05% fluoride and use fluoride gel (Sultan1.23% Fluoride ion, pH = 3.5): The gel is placed in the mouth of the patient once for 60 seconds, according to the manufacturer's recommendation. eating and drinking for 30 minutes after use is prohibited.

Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol School of Dentistry
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Sponsors / Funding sources

1

Sponsor
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Meisam Mirzaie
Position
assistant professor
Latest degree
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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