

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

Study aim

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

Design

A non-randomized, double-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 three-point bending test. 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. Patient who has all the maxillary teeth. Exclusion criteria: Patients who donot 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

Determine the prescription method of fluoride which has

less effect on reducing the desired load-deflection characteristics of rhodium-coated nickel-titanium (NiTi) orthodontic wires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180220038804N1**

Registration date: **2018-04-20, 1397/01/31**

Registration timing: **retrospective**

Last update: **2018-04-20, 1397/01/31**

Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

Mahan Fateh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1408

Email address

M.fateh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-04-08, 1397/01/19

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 load-deflection characteristics 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 theeth.

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 sjogren'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 acide 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

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

In this study, patients were undrestood that the aim of this study is evaluation of the effect of fluoride on orthodontic wires. The patient do not know the type of fluoride prescription to other patients. Also, 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

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2017-03-11, 1395/12/21

Ethics committee reference number

MUBABOL.REC.1395.262

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 "Three-point bending test"

Timepoint

Perform Three-point bending test 6 weeks after placement of wires in the mouth

Method of measurement

Three-point bending test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Use Oral-B fluoride toothpaste twice a day with 0.05% flouride 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

2**Description**

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

Category

Diagnosis

3

Description

Intervention group: Use Oral-B fluoride toothpaste twice a day with 0.05% fluoride and use fluoride gel (Sultan 1.23% 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

Full name of responsible person

Valiollah Arash

Street address

Entefazeh Squire., Babol School of Dentistry

City

Babol

Province

Mazandaran

Postal code

47176-43633

Phone

+98 11 3229 1408

Email

m.fateh@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Ganjafrooz Ave., Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۱۴۵

Phone

+98 11 3219 9592

Email

m.fateh@mubabol.ac.ir

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

Valiollah Arash

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Entefazeh Squire., Babol School of Dentistry

City

Babol

Province

Mazandaran

Postal code

47176-43633

Phone

+98 11 3229 1408

Email

m.fateh@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Valiollah Arash

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Entefazeh Squire., Babol School of Dentistry

City

Babol

Province

Mazandaran
Postal code
47176-43633
Phone
+98 11 3229 1408
Email
m.fateh@mubabol.ac.ir
Web page address

47176-43633
Phone
+98 11 3229 1408
Email
m.fateh@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Valiollah Arash
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Entefazeh Sqre., Babol School of Dentistry
City
Babol
Province
Mazandaran
Postal code

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