

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3233 4389

##### Email address

s.sheikhzadeh@mubabol.ac.ir

##### 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 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 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

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۴۵

**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

**Full name of responsible person**

Meisam Mirzaie

**Street address**

Entefazeh Square., Babol School of Dentistry

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47176-43633

**Phone**

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s.sheikhzadeh@mubabol.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

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Ganjafrooz Ave., Babol University of Medical Sciences

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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**

Specialist

**Other areas of specialty/work**

orthodontics

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assistant professor

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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