

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effectiveness of water and liquid soap solution compared to chlorhexidine on microbial load reduction and microbial plaque formation on orthodontic removable appliances

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of water and liquid soap solution in comparison with chlorhexidine in reducing microbial load and microbial plaque formation on orthodontic removable appliances in order to describing water and liquid soap solution which is easy to access, low cost and has no destructive effects on the appliances for the patients based on scientific documentation.

Design

a cross, one-way blinded, randomized clinical trial without control group. For randomization R software version 3.4.3 is used.

Settings and conduct

This one-way blinded clinical trial (blinding of this study is done with R software version 3.4.3, and the patients are not aware of the solution used to wash the appliances) is conducted in Guilan dental school on 20 patients within the age of 6 to 19 candidate for treatment with orthodontic removable appliances. Sampling is done with 1 week distance, the patients should not use any specific solution on the appliances.

Participants/Inclusion and exclusion criteria

20 patients who are candidate for treatment with maxillary removable orthodontic appliances referred to Guilan dental school and private office regardless of gender and in the age range of 9 to 16 will be selected.

Intervention groups

The intervention in this study includes washing the orthodontic removable appliances with water and liquid soap solution and chlorhexidine solution.

Main outcome variables

Proving the effectiveness of water and liquid soap solution and its comparability with chlorhexidine in reducing microbial load on orthodontic removable appliances.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190915044771N1**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **prospective**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

Yasamin Babaee hemmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3332 0298

Email address

yasi.10482@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of water and liquid soap solution compared to chlorhexidine on microbial load reduction and microbial plaque formation on orthodontic removable appliances

Public title

evaluating the effectiveness of water and liquid soap solution in cleansing of orthodontic removable appliances

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with good general health and good oral hygiene candidate receiving treatment with orthodontic removable appliances

Exclusion criteria:

patients with sever crowding wide diastema periodontal problems severe dental caries or cavities patients using antimicrobial mouthwashes patients who have received antibiotics in last three months patients with poor oral hygiene

Age

From **9 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **7**

The samples are included of samples with sterile swab from patient's palate in each session to determine the index of microbial plaque in the patient and the samples taken from the surface of orthodontic removable appliances before and after the appliance wash at the first session of referral(7 days from beginning) and the second meeting(14 days from beginning).

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation rule is used to assign individuals to two groups. For this reason, considering group A the removable appliances are located in water and liquid soap solution and in group B the removable appliances are located in chlorhexidine solution. Randomization was performed with R software version 3.4.3.

Blinding (investigator's opinion)

Single blinded

Blinding description

performing the washing steps in each visit are done by a trained person and according to the designated protocol and the patient is not aware of the solution for washing, so it is an one-way blind study

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics commiittee of Guilan University of Medical Sciences

Street address

No. 20, Faraz building, Fajr Alley, Namjoo Ave

City

Rasht

Province

Guilan

Postal code

4144693358

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.GUMS.REC.1399.224

Health conditions studied**1****Description of health condition studied**

Evaluating the effectiveness of water and liquid soap solution compared to chlorhexidine on microbial load reduction and microbial plaque formation on orthodontic removable appliances

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

microbial load on orthodontic removable appliance

Timepoint

7 days from beginning, 14 days from beginning

Method of measurement

Stained areas with disclosing agents

2**Description**

microbial load on orthodontic removable appliance

Timepoint

7 days from beginning, 14 days from beginning

Method of measurement

Counting the number of live bacteria

Secondary outcomes

1

Description

Patient's plaque index

Timepoint

At the beginning of study (orthodontic removable appliance delivery session), 7 days from beginning, 14 days from beginning

Method of measurement

Counting the number of live bacteria

Intervention groups

1

Description

Intervention group A : In first referral session the orthodontic removable appliances will be washed with water and liquid soap solution, and in the second session the appliances will be washed with chlorhexidine 0.2%.

Category

Other

2

Description

Intervention group B : Group A interventions for this group will be done in reverse.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan dental school

Full name of responsible person

Dr. Yasamin Babaee hemmati

Street address

Guilan dental school, Fuman, Guilan Province

City

Rasht

Province

Guilan

Postal code

4144693358

Phone

+98 13 3348 6406

Email

yasi.10482@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Guilan University of Medical Sciences, Tehran highway ,Guilan Province

City

Rasht

Province

Guilan

Postal code

4144693358

Phone

+98 13 3348 6406

Email

yasi.10482@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

50

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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Yasamin Babaee Hemmati

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthodontist

Street address

Guilan dental school, Rasht

City

Rasht

Province

Guilan

Postal code

4144693358

Phone

+98 13 3348 6406

Email

yasi.10482@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Yasamin Babae hemmati

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

No.12,Banafshe Ave,Manzarieh Blvd,Rasht

City

Rasht

Province

Guilan

Postal code

4144693358

Phone

+98 13 3332 0298

Fax**Email**

yasi.10482@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Yasamin Babae hemmati

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Orthodontist

Street address

No.12,Banafshe Ave,Manzarieh Blvd,Rasht

City

Rasht

Province

Guilan

Postal code

4144693358

Phone

+98 13 3332 0298

Fax**Email**

yasi.10482@gmail.com

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data in this study can be shared.

When the data will become available and for how long

The beginning of the access period is after 1401

To whom data/document is available

The data of this study will be available for use by other researchers.

Under which criteria data/document could be used

In the case of using the results and methods of this study, the source should be mentioned.

From where data/document is obtainable

Dr. Yasamin Babae Hemmati, Guilan dental school

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

Review and satisfaction of the person responsible for the implementation of this study.

Comments