

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Fixed Orthodontic Appliances on Salivary Changes in Vitamin C in Orthodontic Patients

Protocol summary

Study aim

Evaluation of Fixed Orthodontic Appliances on Salivary Changes in Vitamin C in Orthodontic Patients

Design

This study was randomized clinical trial and 30 patients were on this experiment for third time .once before bracing and then one month and three month after bracing , too see if we have salivary changes in vitamin C or not .

Settings and conduct

Faculty of Dentistry, Azad Islamic university of dental science in Tehran and one private orthodontic clinic in Tehran

Participants/Inclusion and exclusion criteria

Entry requirements: all of patients have to be in need for fixed orthodontic treatments and conditional of non-arrival were patients having lack of entry criterias for follow ups and having no cooperation

Intervention groups

The following measurements were done on all of the patients had criterias and entry requirement. The total number of patients were 30 .and they were third time on the experiments .once before bracing and then one month and three month later after bracing .the patients saliva were carried in plastic sample bottles to laboratory. The Total number of samples was 90 . and they were measured by Atomic Absorption Spectrophotometry .

Main outcome variables

Salivas vitamin C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190109042308N1**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **retrospective**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

Registration date

2019-10-14, 1398/07/22

Registrant information

Name

Sara Rousta

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 7814

Email address

dr.jahaniazadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-23, 1395/07/02

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2017-06-25, 1396/04/04

Actual recruitment end date

2018-04-21, 1397/02/01

Trial completion date

2018-04-21, 1397/02/01

Scientific title

Evaluation of Fixed Orthodontic Appliances on Salivary Changes in Vitamin C in Orthodontic Patients

Public title

The Effect of Fixed Orthodontic Appliances on Salivary Changes in Vitamin C in Orthodontic Patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should be in need of orthodontic treatment
The patient should be case of only fixed orthodontic treatment at the time of project

Exclusion criteria:

The patient that does not want to cooperate on the project

Age

From **12 years** old to **38 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Faculty of Dentistry Islamic Azad University, Tehran Branch

Street address

Islamic Azad University, 9th neyestan ,pasdaran street,Tehran

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.IAU.DENTAL.REC.1396.6

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vitamin c of saliva

Timepoint

Before bracing, one month and three months after bracing

Method of measurement

Atomic absorption spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

To see how much do we have changes in mount of Vitamin C of saliva in patients with fixed orthodontic appliances . We had to give all the patients fixed orthodontic appliances such as aces/ligatures/wires. the examinations of saliva were before giving patients braces as primary amount of vitamin C in saliva,1 month after bracing ,and the last examination was on 3 month after bracing)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic Clinic in Islamic Azad University

Full name of responsible person

Dr. Ahmad Sheibani Nia

Street address

Islamic Azad University, Boostan 9 valley, Pasdaran street

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Email

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Web page address

<http://dental.iaumu.ac.ir>

2

Recruitment center

Name of recruitment center

Valiasr Dental Clinic

Full name of responsible person

Dr. Azadeh Jahani

Street address

No. 2417, Valiasr street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ahmad Sheybani Nia

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sara rousta (researcher)

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Dr Ahmad Shebani Nnia

Position

Orthodontic proffesor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ahmad Sheybani Nia

Position

University professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sara Rousta

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

changing of salivas vitamin C

When the data will become available and for how long

1 year

To whom data/document is available

profesores and students

Under which criteria data/document could be used

After defence and main presentation in university

From where data/document is obtainable

irct.ir and university site

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

inter in irct.ir

Comments