

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Bisphenol Release in Saliva after Remaining Adhesive Removal in Orthodontic Patients Using Ultrasonic and Rotary Systems

Protocol summary

Study aim

Determining and comparing the amount of bisphenol A in saliva after removal of residual adhesive with ultrasonic scaler and rotary system

Design

Clinical trial with two parallel groups with different interventions, single blind, randomized, phase 2 on 40 patients. Randomization is done using Random allocation software (RAS).

Settings and conduct

In this study, 40 patients referred to the specialized department of Tabriz Dental School who receive fixed orthodontic treatment are randomly placed in two groups of 20 people. All patients with metal brackets and Light Cure composite and bonding will be treated. After the brackets are debonded with a plier, by the method of pulling the brackets through the plier, removing the adhesive residue from the surface of the tooth in the first group will be completely performed by an ultrasonic scaler and In the second group, first by a turbine with a carbide cone bur machine a large volume of adhesive will be removed and then the residual layer near the enamel will be removed by a low speed handpiece with a tungsten carbide bur. Then, using a calibrated pipette, 1 cc of saliva is collected from the vestibular buccal and sub lingual areas and stored in glass vials. High-performance liquid chromatography / mass spectrometer will be used to determine the level of bisphenol A.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with at least 16 bonded teeth.
Exclusion criteria: Tobacco use (chewable and absorbable); Liver disease; Kidney disease; Taking drugs containing phenolic compounds.

Intervention groups

The first group: removal of adhesive with a rotary system
The second group: removal of adhesive with ultrasonic scaler

Main outcome variables

The amount of bisphenol identified in saliva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200702047988N1**

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

Registration timing: **retrospective**

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

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

Sara Seifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5969

Email address

seifis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-06-29, 1397/04/08

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2018-06-29, 1397/04/08

Trial completion date

2018-06-29, 1397/04/08

Scientific title

Evaluation of Bisphenol Release in Saliva after Remaining Adhesive Removal in Orthodontic Patients Using Ultrasonic and Rotary Systems		Street address Department of Orthodontics, School of Dentistry ,Golgasht street ,Tabriz
Public title Evaluation of Bisphenol Release in Saliva after Remaining Adhesive Removal in Orthodontic Patients Using two different methods		City Tabriz
Purpose Supportive		Province East Azarbaijan
Inclusion/Exclusion criteria Inclusion criteria: Patients with at least 16 bonded teeth in the mouth Exclusion criteria: Tobacco use Liver diseases Kidney diseases Taking drugs containing phenolic compounds		Postal code 5157955359
Age No age limit		Approval date 2020-06-01, 1399/03/12
Gender Both		Ethics committee reference number IR.TBZMED.REC.1399.186
Phase N/A		
Groups that have been masked <i>No information</i>		Health conditions studied
Sample size Target sample size: 40 Actual sample size reached: 40 More than 1 sample in each individual Actual sample size in each individual: 20 20 patient in each method		<u>1</u> Description of health condition studied Evaluation of bisphenol identified in saliva of orthodontic patients after debonding with two methods: Rotary system and ultrasonic scaler
Randomization (investigator's opinion) Randomized		ICD-10 code ICD-10 code description
Randomization description Randomization is done using Random allocation software (RAS) by writing the number of groups and the sample size in the specified field and clicking on the generate random list option gives each sample a code in which The group is placed. Allocation concealment as Sequentially numbered, opaque, sealed envelopes (SNOSE); is.The sealed envelopes are given to the ward secretary and she registers the patients		Primary outcomes
Blinding (investigator's opinion) Not blinded		<u>1</u> Description The amount of Bisphenol
Blinding description		Timepoint End of treatment
Placebo Not used		Method of measurement high-performance liquid chromatography/mass spectrometr device
Assignment Parallel		Secondary outcomes empty
Other design features		Intervention groups
Secondary Ids empty		<u>1</u> Description Intervention group1: Removing the adhesive with ultrasonic
Ethics committees		Category Treatment - Devices
<u>1</u> Ethics committee Name of ethics committee Ethics committe of Tabriz University of Medical Sciences		<u>2</u> Description Intervention group 2: Removing the adhesive with rotary system Category Treatment - Devices
		Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz School of Dentistry

Full name of responsible person

Behnam Mirzakoochaki

Street address

Department of Orthodontics ,School of Dentistry
,Golgasht street ,Tabriz

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Tabriz

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mozhgan Kachoei

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School of Dentistry, Golgasht street ,Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sara Seifi

Position

Resident of Orthodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Total data is shareable

**When the data will become available and for how
long**

Start the access period 6 months after printing the
results

To whom data/document is available

It will be available to everyone

Under which criteria data/document could be used

Academic and job information

From where data/document is obtainable

sara.seifi70@yahoo.com

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

Up to 1 month after requesting data

Comments