

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Investigating the effects of mucosal adhesives containing resveratrol on gingival inflammation indexes in patients undergoing fixed orthodontic treatment

#### Protocol summary

##### Study aim

Investigating the effects of mucosal adhesives containing resveratrol on gingival inflammation indexes in patients undergoing fixed orthodontic treatment

##### Design

This study is a blind clinical trial. The study population included all patients referring to the School of Dentistry in Kermanshah city. 60 eligible patients will be selected conveniently and randomly assigned to three intervention groups.

##### Settings and conduct

This study, which will be carried out at Kermanshah city Dental School, is a blinded one, so that the participants do not know what medicine they will receive. At the beginning of the study, The plaque status, gingival and periodontal indexes are recorded in a checklist in all three groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of severe periodontal disease or periodontal surgery  
Exclusion criteria: severe gingival bleeding

##### Intervention groups

The first intervention group received an orthodontic device without using a mucosal adhesive containing resveratrol. The second intervention group will receive an orthodontic device with using a mucous adhesive containing 1% resveratrol and for 14 nights will use the mucous adhesive routinely after the brushing, every night. The third intervention group will receive an orthodontic device with using a mucous adhesive containing 2% resveratrol and for 14 nights will use the mucous adhesive routinely after the brushing, every night.

##### Main outcome variables

Plaque status ; Gingival bleeding; Periodontal

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N91**

Registration date: **2018-05-19, 1397/02/29**

Registration timing: **prospective**

Last update: **2018-05-19, 1397/02/29**

Update count: **0**

##### Registration date

2018-05-19, 1397/02/29

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-26, 1397/03/05

##### Expected recruitment end date

2018-07-27, 1397/05/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the effects of mucosal adhesives containing resveratrol on gingival inflammation indexes in patients undergoing fixed orthodontic treatment

### Public title

Investigating the effects of mucosal adhesives on gingival inflammation indexes in patients undergoing fixed orthodontic treatment

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

No history of severe periodontal disease or periodontal surgery  
The need for fixed orthodontic treatment  
Do not use drugs or mouthwashes  
Not having a systematic illness  
Age between 10 to 18 years

#### Exclusion criteria:

Severe gingival bleeding

### Age

From **10 years** old to **18 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Approval date

2018-03-14, 1396/12/23

##### Ethics committee reference number

ir.kums.rec.1396.700

## Health conditions studied

### 1

#### Description of health condition studied

Gingival inflammation

#### ICD-10 code

K05

#### ICD-10 code description

Gingivitis and periodontal diseases

## Primary outcomes

### 1

#### Description

Plaque status

#### Timepoint

The beginning and end of the study

#### Method of measurement

Based on the gingival index (GI)

### 2

#### Description

Bleeding of gingival

#### Timepoint

The beginning and end of the study

#### Method of measurement

Based on the gingival bleeding index (GBI)

### 3

#### Description

Periodontal

#### Timepoint

The beginning and end of the study

#### Method of measurement

Using periodontal probes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group received an orthodontic device without using a mucosal adhesive containing resveratrol

#### Category

Treatment - Other

## 2

### Description

The second intervention group will receive an orthodontic device with using a mucous adhesive containing 1% resveratrol and for 14 nights will use the mucous adhesive routinely after the brushing, every night, .

### Category

Treatment - Other

## 3

### Description

The third intervention group will receive an orthodontic device with using a mucous adhesive containing 2% resveratrol and for 14 nights will use the mucous adhesive routinely after the brushing, every night,

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry

##### Full name of responsible person

Fatemeh Ghorbani

##### Street address

Shariati Avenue - above Shura Street, Faculty of Dentistry

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 83 3722 2400

##### Email

f\_ghorbani@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Farid Najafi

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

fnajafi@kums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Fatemeh Ghorbani

##### Position

MSc Biochemistry

##### Latest degree

Master

##### Other areas of specialty/work

Biochemistry

##### Street address

Shariati Avenue - above Shura Street, Faculty of Dentistry

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 37222400

##### Email

F\_ghorbani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Amin Golshah

##### Position

Faculty Member of Kermanshah University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shariati Avenue - above Shura Street, Faculty of Dentistry

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**Province**

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**Phone**

+98 83 3722 2400

**Email**

f\_Ghorbani@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

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

6 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Fatemeh Ghorbani

**Position**

MSc Biochemistry

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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Kermanshah

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