

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

A clinical trial to compare the effectiveness of ceramic bur with surgical scalpel for gingivectomy in fixed orthodontic patients

Protocol summary

Study aim

To compare the effectiveness of ceramic bur with surgical scalpel for gingivectomy in fixed orthodontic patients.

Design

Totally, 40 patients with gingival enlargement who undergoing fixed orthodontic treatment in the Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran are selected in this study. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using random SAS computer software methods.

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to the Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged range 15-25 years; non-smoking; patients with gingival enlargement despite the use of health tips and mouthwash; the gingival enlargement cannot be treated with drugs. Exclusion criteria: Patients treatment of drug-induced gingival enlargement; pregnant and breastfeeding women.

Intervention groups

The intervention group will receive the ceramic soft tissue trimming bur method with a turbine and without cooling for gum contouring. The control group will receive surgical scalpel as a routine method for gum contouring.

Main outcome variables

wound healing Index, gingival index, gingival bleeding index, and pain score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048874N1**

Registration date: **2020-10-19, 1399/07/28**

Registration timing: **prospective**

Last update: **2020-10-19, 1399/07/28**

Update count: **0**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

Zahra Siadatifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

omidkhodam1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of ceramic bur with surgical scalpel for gingivectomy in fixed orthodontic patients

Public title

The effectiveness of ceramic bur for gingivectomy in fixed orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged range 15-25 years Non-smoking Patients with gingival enlargement despite the use of health tips and mouthwash The gingival enlargement cannot be treated with drugs

Exclusion criteria:

Patients treatment of drug-induced gingival enlargement Pregnant and breastfeeding women

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly assigned into three groups of 20 patients with categories of 2 and 4 using the randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned into the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients whose undergoing orthodontic treatment and referring to the Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, code was allocated to each of the participants and the person responsible for data collection is blind to group allocation and the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.052

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

Patients with gingival enlargement who undergoing fixed orthodontic

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes**1****Description**

Wound healing Index

Timepoint

2 hours, as well as 1, 3, 5, 7, and 14 days after intervention

Method of measurement

Photography images

2**Description**

Gingival index

Timepoint

2 hours, as well as 1, 3, 5, 7, and 14 days after intervention

Method of measurement

Base on gingival overgrowth Index

3**Description**

Gingival bleeding index

Timepoint

2 hours, as well as 1, 3, 5, 7, and 14 days after intervention

Method of measurement

Base on bleeding point index

Secondary outcomes

1

Description

Pain score

Timepoint

2 hours, as well as 1, 3, 5, 7, and 14 days after intervention

Method of measurement

Base on Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: Intervention group will receive the ceramic soft tissue trimming bur method with a turbine and without cooling for gum contouring.

Category

Treatment - Surgery

2

Description

Control group: Control group will receive surgical scalpel as a routine method for gum contouring.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Zahra Siadatifar

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
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9177948959

Phone

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Email

szahrasiadatifar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
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9138813944

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+98 51 3841 1538

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Siadatifar

Position

Student

Latest degree

A Level or less

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

Contact

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities.

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

Zahra Siadatifar provides the data analysis to the applicants via email: szahrasiadatifar@gmail.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

Comments