

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of Plaque Removal and Gingival Abrasion between Soft and Medium Toothbrushes in Patients with Gingivitis

Protocol summary

Summary

(1) The goal of this study is to assess plaque removal and gingival abrasion by soft and medium toothbrushes in patients suffering from gingivitis. (2) In this study, which is a randomized, double-blinded clinical trial, (3) teeth of people suffering from gingivitis, who will be included in the trial after signing written consent, will be divided into four quadrants. (4) Inclusion criteria: no history of systemic diseases; no history of periodontal treatment during the last year; sulcus depth of 3mm or less; number of present teeth over 20; diagnosis of gingivitis and plaque index of more than 50. Exclusion criteria: patient unwillingness or failure to cooperate; use of antibiotics or chemical plaque control methods; receiving periodontal treatment. (5) After scaling, all patients receive one soft and one medium toothbrushes and will brush each quadrant with one of them in the form of a cross for four weeks. (6) Finally, the amount of plaque, gingival index, and extent of gingival abrasion will be compared between the quadrants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100836648N1**
Registration date: **2017-11-16, 1396/08/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Zahra Sohrabi

Name of organization / entity

Kermanshah University of Medical Sciences - School of Dentistry

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Committee of Ethics in Research - Kermanshah University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Plaque Removal and Gingival Abrasion between Soft and Medium Toothbrushes in Patients with Gingivitis

Public title

Comparison of Cleansing Ability and Gum Abrasion from Soft and Medium Toothbrushes in Patients with Inflamed Gum

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: No history of systemic diseases such as diabetes, etc. ; No history of periodontal treatment during the last year; Sulcus depth of 3 millimeters or less; Presence of no abrasion or recession in the gingiva;

Number of present teeth over 20; Diagnosis of gingivitis and plaque index of 50 percent or more according to O'leary index. Exclusion criteria: Patient non-compliance; Leaving the trial by patients; Use of antibiotics during the trial; Use of chemical plaque control methods during the trial; Patients receiving any other type of periodontal treatment during the trial.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary IDs**

empty

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

Committee of Ethics in Research - Kermanshah University of Medical Sciences

Street address

Committee of Ethics in Research, Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Postal code

6715847167

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

KUMS.REC.1396.118

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

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Gingivitis (chronic)

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

Plaque index

Timepoint

Prior to intervention, 4 weeks after intervention

Method of measurement

Using O'leary index in percent

2**Description**

Danser gingival abrasion index

Timepoint

Prior to intervention, 4 weeks after intervention

Method of measurement

Using Danser gingival abrasion index, in mean area per tooth

3**Description**

Gingival index

Timepoint

Prior to intervention, 4 weeks after intervention

Method of measurement

Using gingival index, based on extent of bleeding on probing from 0 to 4

Secondary outcomes

empty

Intervention groups**1****Description**

Use of medium toothbrush

Category

Prevention

2**Description**

Use of soft toothbrush

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Dentistry, Kermanshah University of Medical

Sciences, Kermanshah, Iran

Full name of responsible person

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research and technology,
Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences, Shahid
Beheshti Blvd.

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Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research and technology,
Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences - School
of Dentistry

Full name of responsible person

Zahra Sohrabi

Position

Assistant professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty