Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical comparison of two types of dental floss on interdental plaque removal and gingival health

Protocol summary

Study aim
Clinical comparison of two types of dental floss on interdental plaque removal and gingival health

Design
double_blind clinical trial , with parallel groups , randomized , phase 3 on 50 people

Settings and conduct
this study is a randomized clinical trial on 50 dental students of Kurdistan University of Medical Sciences.The patients are selected according to the entry and exit criteria. The patients are divided into two groups of 25. The first group was given expanding dental floss and the second group was given simple waxed dental floss, and the patients asked to use it twice a day, morning and night, for 6 weeks. Then, four scales are used to measure the amount of dental plaque, gingivitis and bleeding on probe.

Participants/Inclusion and exclusion criteria
Entry conditions: patients with generalized gingivitis and plaque index below 2 Conditions of non-entry: use of drugs affecting periodontium, pregnancy, use or history of smoking, malocclusion, history of orthodontic treatment, oral mucosa disease, people with chronic systemic diseases (copulative diseases, kidney diseases, diabetes and any other diseases) which affects the periodontal condition of the person), depth of pocket more than 3 mm, use of antibiotics, use of mouthwash, periodontal surgery in the last 6 months, the presence of calculus below and above the gums

Intervention groups
patients are randomly divided in two groups.(A expanding floss and B simple waxed floss)

Main outcome variables
interdental plaque , gingival health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220726055559N3**
Registration date: **2023-11-09, 1402/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-09, 1402/08/18**
Update count: **0**

Registration date
2023-11-09, 1402/08/18

Registrant information

Name
Shabnam Khalifehzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3362 2260

Email address
shabnam.kh63ii@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-08, 1402/08/17

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical comparison of two types of dental floss on interdental plaque removal and gingival health

Public title

comprasion the effect of two types of dental floss on interdental plaque

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with generalized gingivitis Plaque index< 2

Exclusion criteria:

History of orthodontic treatment patients with systemic chronic diseases patients with oral mucosal diseases periodontal surgery in last 6 months

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The purpose of block randomization is that equal number of participants enter the intervention and control groups. The size of each block is 25 people. In this way, expanding floss is assigned to the first block and simple waxed floss to the second block to be.

Blinding (investigator's opinion)

Double blinded

Blinding description

expanding floss and simple waxed floss are named with two letters B&A and will be given to two equal groups of patients. The patients are selected with the minimum entry criteria. There are 25 patients in each group. It will be fully explained to the patients. Written informed consent will be obtained from the patients. The patients will be selected by sampling based on the entry criteria and will be randomly divided into two equal groups. Group A is expanding floss and the group B will use simple waxed floss. Participants and health personnel will not know the type of toothpaste.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Science

Street address

Kurdistan University of Medical Science, Pasdaran Ave

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sanandaj

Province

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Postal code

661713446

Approval date

2023-08-28, 1402/06/06

Ethics committee reference number

IR.MUK.REC.1402.133

Health conditions studied

1

Description of health condition studied

interdental plaque

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes

1

Description

interdental plaque and gingival health

Timepoint

Measure the indexes at the beginning of the study, 21 and 42 days later

Method of measurement

PI (Silness_Loe plaque index) with 0-3 score . IPI (interdental pressure index) with posetive and negetive . GI(Silness_loe gingival index) with 0-4 score . PBI (papillary bleeding index) with 0-4 score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: AThey receive expanding floss.They use floss twice a day for 42 days .

Category

Treatment - Drugs

2

Description

Intervention group: B AThey receive simple waxed floss.They use floss twice a day for 42 days .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kurdistan University of Medical Sciences

Full name of responsible person
zahra zabihi rizi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
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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
Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
zahra zabihi rizi

Position
dental student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Position

dental student

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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