

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The assessment of effect of commercial chlorhexidine and conventional tooth flosses on gingivitis reduction: Randomized clinical trial

Protocol summary

plaque index, gingival index, bleeding on probing index

Study aim

The assessment of effect of commercial chlorhexidine and conventional tooth flosses on gingivitis reduction:
Randomized clinical trial

Design

This study will be performed in the center of the Faculty of Dentistry of Ardabil University of Medical Sciences, as a triple-blind (patient, researcher and study analyst) and as a randomized clinical trial.

Settings and conduct

students studying at Dental School, 50 people who meet the set criteria will participate in the study after receiving written consent. each person is given the necessary training and they are asked to use the given dentures as a split mouth. After a period of time, the studied indicators will be evaluated. Finally, the effect of commercial chlorhexidine floss and conventional floss in reducing gingivitis will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lack of systemic disease, Existence of (BOP) in at least one dental space in each quadrant, Maximum pocket depth is 2 mm and no gingival recession, Gingival index Loe & Sillness more than 1.5, At least 5 teeth per quadrant, Maximum interdental space is 1 mm
Exclusion criteria: smoking, Use of any type of dental appliance, blocking agent other than calculus, Use of systemic antibiotics in the last 3 months before, Use of drugs that affect the condition of the gums, Chronic use of nonsteroidal anti-inflammatory drugs (NSAIDs), Consumption of mouthwash in the last 6 months, Systemic diseases that cause changes in periodontal health, such as: diabetes, hormonal problems, patients at risk for endocarditis, pregnant women and nursing mothers, Existence of oral diseases other than gingivitis, parafunctional habits, malocclusion

Intervention groups

Intervention group: commercial chlorhexidine floss
Control group: conventional floss

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210305050584N1**

Registration date: **2021-11-17, 1400/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-17, 1400/08/26**

Update count: **0**

Registration date

2021-11-17, 1400/08/26

Registrant information

Name

Sheida Fazlalizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3324 9753

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-21, 1400/07/29

Expected recruitment end date

2022-03-18, 1400/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of effect of commercial chlorhexidine and conventional tooth flosses on gingivitis reduction: Randomized clinical trial

Public title

The assessment of effect of commercial chlorhexidine and conventional tooth flosses on gingivitis reduction: Randomized clinical trial

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of systemic disease Existence of bleeding on probing (BOP) in at least one dental space in each quadrant (one quarter of the jaw) Maximum pocket depth is 2 mm and no gingival recession Gingival index loe & sillness more than 1.5 At least 5 teeth per quadrant Maximum interdental space is 1 mm

Exclusion criteria:

smoking Use of any type of dental prosthesis appliance, orthodontics, cavities or any plaque blocking agent other than calculus Use of systemic antibiotics in the last 3 months before the start of the study Use of drugs that affect the condition of the gums. Chronic use of nonsteroidal anti-inflammatory drugs (NSAIDs) Consumption of mouthwash in the last 6 months Systemic diseases that cause changes in periodontal health, such as diabetes, hormonal problems, patients at risk for endocarditis, pregnant women and nursing mothers. Existence of oral diseases other than gingivitis parafunctional habits malocclusion

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 51

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of samples is done using sealed envelopes. Inside the envelopes, half of the samples contain an A card and half of the samples contain a B card, and the samples randomly pick up a card from the envelope. Each specimen that removes card A will floss its right quadrant (quadrant) with chlorhexidine floss and its two left quadrant with conventional floss, and each specimen that removes card B will floss its two right quadrant with conventional floss and two left quadrants

will floss with chlorhexidine floss.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Both types of floss are selected with similar packages and covered with the same labels (sample blinding). The analyst of the study data and the person measuring the indexes (researcher) do not know in which group the samples are.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical science

Street address

Daneshgah Ave, Ardabil university of medical sciences

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.ARUMS.REC.1400.236

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Plaque index

Timepoint

Baseline and 2,4,8 weeks after intervention

Method of measurement

Turesky modified Quigley-hein index

2

Description

Gingival index

Timepoint

Baseline and 2,4,8 weeks after intervention

Method of measurement

Löe&Sillness gingival index

3

Description

Bleeding on probing index

Timepoint

Baseline and 2,4,8 weeks after intervention

Method of measurement

Ainamo&Bay bleeding on probing index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use chlorhexidine toothfloss once a day before sleeping for 2 months.

Category

Prevention

2

Description

Control group: Use c conventional toothfloss once a day before bed for 2 months.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil University of Medical science-Dentistry
Faculty

Full name of responsible person

Dr.Sheida Fazlalizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil 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?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Sheyda Fazlalizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sheyda Fazlalizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mehdi Hosseinzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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

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

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

Title and more details about the data/document

part of datas

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutes can request access to data and documents only for the purpose of scientific and research work and in order to improve scientific resources.

From where data/document is obtainable

Sheyda Fazlalizadeh, sh.fazlalizade@gmail.com Mehdi Hosseinzadeh, m.hosseinzadeh9776@gmail.com

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

Requests will be answered via email as soon as possible.

Comments