Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

plaque index, gingival index, bleeding on probing index

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
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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 updating data

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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