

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Study the Effect of eucalyptus chewing gum on reduction of microbial plaque of dental students

Protocol summary

Study aim

determining the effect of chewing Eucalyptus gum on accumulation of microbial plaque on different surfaces of tooth.

Design

Study is a crossover randomized clinical trial with control group, Not Randomized, Not blinded

Settings and conduct

study is conducted over two 3-day period with a 4-day break between them in dental clinic of Hormozgan university of medical science. At the beginning of each period individuals' Plaque index is measured and then according to the protocol they are given gum; after the end of each period, individuals' plaque index will be measured again.

Participants/Inclusion and exclusion criteria

participants should have full oral and dental health(without rampant caries and bleeding on probing) and without underlying disease,without orthodontic brackets and without severe dental crowding

Intervention groups

Intervention group1: They chew 4 pieces of gums contain Eucalyptus extract(Orbit ,Wrigley company) for 20 minutes after main meals and 1 piece after afternoon snack daily(for 3 days) Intervention group2: They chew 4 pieces of plain gums from same company for 20 minutes after main meals and 1 piece after afternoon snack daily(for 3 days) Because the study is crossover design so each intervention group is its control too so in the second period which is 4 days after first period , intervention and control group will switch and the process will repeat.

Main outcome variables

Accumulated dental plaque on different dental surfaces

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190715044223N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

Sara Achangan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3223 4030

Email address

sara.achangan@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effect of eucalyptus chewing gum on reduction of microbial plaque of dental students

Public title

The effect of Eucalyptus chewing gum on microbial plaque

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants should have full oral and dental health (without rampant caries and bleeding on probing) Individuals without underlying disease Individuals without orthodontic brackets Individuals without severe dental crowding

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization method. We use a block size of 4 to do this and we assume that we have gum A and gum B ;There are 6 possible arrangement for blocks : AABB - ABAB - BAAB - BABA - BBAA - ABBA .We randomly choose one block for example ABAB , Then we enroll 30 participants and number them from 1 to 30 ;Then for the first four participants we choose this permuted block randomization scheme: ABAB : gumA=participant1 /gumB=participant2 / gumA=participant3 / gumB=participant4 Then we randomly choose another block for the participants number 5 to 8 ; Then this trend will be repeated.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of Hormozgan University of Medical Sciences

Street address

19th Rahil alley , Shahid kazerouni street

City

Bandarabbas

Province

Hormozgan

Postal code

7914857179

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.HUMS.REC.1397.325

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

Accumulation of microbial plaque

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Accumulated dental plaque on different dental surfaces

Timepoint

Before the beginning of the intervention and after the third day of each period

Method of measurement

Dental plaque measurement using Detector tablets on smooth surfaces using O'Leary index and M.Addy in occlusal surface

Secondary outcomes

empty

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

Intervention group1: half of the participants during a 3-day period use 4 pieces of Eucalyptus gum daily (Orbit Wrigley company) for 20 minutes after meals and 1piece after afternoon snack , after 4 days of wash out period ,participants during a 3-day period use 4 pieces of plain gum as placebo (Orbit Wrigley company) daily for 20 minutes after main meals and 1piece after afternoon snack.

Category

Diagnosis

2**Description**

Intervention group2: half of the participant during a 3-day period use 4 pieces of plain gum as placebo (Orbit Wrigley company) daily for 20 minutes after main meals and 1piece after afternoon snack. after 4 days of wash out period , participants during a 3-day period use 4 pieces of Eucalyptus gum daily (Orbit Wrigley company) for 20 minutes after meals and 1piece after afternoon

snack
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental clinic of Hormozgan Univrsity of medical science
Full name of responsible person
Sara Achangan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Research and Technology Dept., East Side of Shahid Mohammadi Hospital, Islamic Republic of Iran Blvd., Bandar Abbas
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Web page address
<https://resv.hums.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Sara Achangan
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Fax**Email**

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