Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of chewing gum on the formation of plaque on the smooth surface theeth

Protocol summary

Study aim
Determine the effect of chewing gum on the formation of plaque in smooth surfaces
Design
In this study, 18 people with complete oral and dental health who are eligible for entering the study are chosen among people who refer to the dental school.
Participants are randomly divided into intervention and control groups and each participant is assigned a code.
Settings and conduct
This study is performed on a randomized clinical trial in the dental school. This study is done in a one-way blind fashion, so that someone who measures the indexes is not aware that which group have used gum and which group is without chewing gum.
Participants/Inclusion and exclusion criteria
The participants are from the dental faculty Entry requirements: Full health of the mouth and teeth
Conditions of non-entry: People with underlying disease and rapidly progressive caries and orthodontic bracket and severe dental arrhythmias
Intervention groups
Case group: A group giving them chewing gum. Control group: A group that does not have chewing gum.
Main outcome variables
O'Leary index: Measuring dental plaque on smooth surfaces Bleeding index: Assessment of bleeding gums around each tooth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171015036782N4**
Registration date: **2018-04-28, 1397/02/08**
Registration timing: **retrospective**
Last update: **2018-04-28, 1397/02/08**
Update count: **0**
Registration date
2018-04-28, 1397/02/08

Registrant information
Name
farzane vaziri
Name of organization / entity
Shahid sadoughi dental university
Country
Iran (Islamic Republic of)
Phone
+98 35 3620 4764
Email address
f.vaziri@ssu.ac.ir

Recruitment status
Recruitment complete
Funding source
Shahid Sadoughi University of Medical Sciences Yazd

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of chewing gum on the formation of plaque on the smooth surface theeth

Public title
The effects of chewing gum on the formation of plaque on the smooth surface theeth
Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Full health of the mouth and teeth

Exclusion criteria:

Underlying disease and rapidly progressive caries with orthodontic bracket and severe dental irregularities

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random allocation software, so 18 eligible patients randomly divide into two groups of 9 patients with making special codes.

Blinding (investigator's opinion)

Not blinded

Blinding description

The outcome evaluator The person who measures the indexes does not know which group is chewing gum and which group is not chewing gum.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

yazd.Bahonar Square

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

ir.ssu.rec.1396.69

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

bleeding index

Timepoint

Once at the end of the period

Method of measurement

Evaluation of the bleeding gingiva around each tooth as percentage

2

Description

o,leary index

Timepoint

Once at the end of the period

Method of measurement

Measuring dental plaque on flat surfaces as percentages

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, for the two days of intervention, they receive four BIODENT chewing gum made in Iran, which can be used for 20 minutes after three meals and one after evening snack.

Category

Prevention

2

Description

The control group does not receive any intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental college

Full name of responsible person
Farzaneh al-Sadat Vaziri
Street address
End of Imam Street, Imam Reza Square, Imam Reza Blvd.
City
yazd
Province
Yazd
Postal code
8914815667
Phone
+98 35 3625 0344
Email
F.VAZIRI@SSU.AC.IR

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Amir Houshang Mehrparvar
Street address
Yazd Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3726 3733
Email
ah.mehrparvar@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Farzaneh al-Sadat Vaziri
Position
Periodontology specialist / assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Street address
End of Imam Street, Imam Reza Square, Imam Reza Blvd.
City
Yazd
Province
Yazd
Postal code
8914815667
Phone
+98 35 3625 0344
Fax
Email
www.f.vaziri@ssu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Farzaneh al-Sadat Vaziri
Position
Periodontology specialist / assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Street address
Yazd Green Space Faculty of Dentistry
City
Yazd
Province
Yazd
Postal code
8914815667
Phone
+98 35 3625 5881
Fax
Email
www.f.vaziri@ssu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Farzaneh al-Sadat Vaziri
Position
Periodontology specialist / assistant professor
Latest degree
Specialist
Other areas of specialty/work

Street address
End of Imam Street, Imam Reza Square, Imam Reza Blvd.
City
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Province
Yazd
Postal code
8914815667
Phone
+98 35 3625 5881
Fax
Email
www.f.vaziri@ssu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
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
Title and more details about the data/document
The whole data is shared
When the data will become available and for how long
5 months after the publication of the article
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Email, phone call
From where data/document is obtainable
Maryam al-Sadat Kamal al-Dini 09131584672 kamaladdini1373@gmail.com
What processes are involved for a request to access data/document
After sending the data, the data will be transmitted
Comments