

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of Propolis-containing chewing gum in comparison with Propolis-containing mouthwash on reducing gingival inflammation in patients with gingivitis

Protocol summary

Study aim

Determining the effect of Propolis containing gum in comparison with Propolis containing mouthwash on reducing gingival inflammation in patients with gingivitis referred to Yazd Dental School in the academic year 1401-1400

Design

Clinical trial with 2 intervention groups, parallel group, non-blind, randomized groups using random number table, on 20 patients

Settings and conduct

20 patients aged 18 to 65 years diagnosed with gingivitis among those referred to the periodontics Department of Yazd Dental School and need SRP after oral examination by a dentist will enter the study. Patients are randomly divided in two groups: each group includes 10 patients with gingivitis. One group is given a propolis mouthwash and we asked them to gargle it twice a day for 1 week and the other group is given propolis containing gum and we asked them to use gum 3 times a day after each meal for 20 minutes for 1 week; and at the end we examine the effects of these substances containing propolis on their plaque index, gingival index and papillary bleeding index .

Participants/Inclusion and exclusion criteria

Patients with gingivitis referred to the periodontics Department of Dental School, no systemic diseases, no sensitivity to mouthwash or Propolis containing gum, no smoking, not during pregnancy and lactation, not taking antibiotics, not using other gums during the study and presence of at least 20 teeth (presence of posterior teeth): No-cooperation in the use of mouthwash or Propolis containing gum

Intervention groups

Patients are examined in two groups: each group includes 10 patients with gingivitis. One group is given a propolis mouthwash and the other group is given

propolis containing gum and at the end we examine the effects of these substances containing propolis on their gingivitis.

Main outcome variables

plaque index: gingival index: papillary bleeding index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220420054592N1**

Registration date: **2022-06-11, 1401/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-11, 1401/03/21**

Update count: **0**

Registration date

2022-06-11, 1401/03/21

Registrant information

Name

Arezou Khabazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 5881

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Propolis-containing chewing gum in comparison with Propolis-containing mouthwash on reducing gingival inflammation in patients with gingivitis

Public title

The effect of Propolis-containing chewing gum in comparison with Propolis-containing mouthwash on reducing gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with gingivitis referred to the periodontics Department of Dental School no systemic diseases no sensitivity to mouthwash or Propolis containing gum no smoking not during pregnancy and lactation not taking antibiotics not using other gums during the study presence of at least 20 teeth (presence of posterior teeth)

Exclusion criteria:

No-cooperation in the use of mouthwash or chewing Propolis containing gum

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Number Table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

ethics committee of Yazd University of Medical Sciences

Street address

School of dentistry, Imam Reza blvd., Imam street, Yazd

City

Yazd

Province

Yazd

Postal code

8914815667

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.015

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

Gingivitis

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

Plaque index

Timepoint

In the first session and 7 days after using Propolis

Method of measurement

O'Leary index and a detector tablet

2**Description**

Gingival index

Timepoint

In the first session and 7 days after using Propolis

Method of measurement

A probe and the principles of the gingival index system specified by Loe

3**Description**

Papillary bleeding index

Timepoint

In the first session and 7 days after using Propolis

Method of measurement

A probe and record the bleeding points around each tooth

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Propolis mouthwash, 30% extract, gargle with Propolis mouthwash (produced by Soren Tak Toos Company of Mashhad) twice a day for 1 minute each time at home for 1 week. We ask them not to eat or drink for 30 minutes after using mouthwash.

Category

Treatment - Drugs

2

Description

Intervention group: Propolis gum, Natural gum base, Xylitol, Maltitol, Mannitol, Glycerine, Lecithin, Propolis, use Propolis gum (a product of Saqez manufacturing company Kurdistan (van) Sanandaj) at home 3 times a day after each meal for 20 minutes (a total of 1 hour a day) for 1 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Dental School

Full name of responsible person

Arezoo Khabazian

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Email

arezookhabazian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hooshang Mehrparvar

Street address

Central Department of Shahid Sadouhhi University of Medical Science , Bahonar Blve, Yazd

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Ah.mehrpavar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Hosein Tabatabaei

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Emam Reza Ave, Dahe Fajr Blvd

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Email

Taba48971@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

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

Email

arezookhabazian@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Arezoo Khabazian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Person responsible for scientific inquiries

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

اطلاعات بیشتری وجود ندارد

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