

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of gum containing petal extract of crocus sativus on gingival inflammation in fixed orthodontic patients

Protocol summary

Study aim

Determining and comparing the rate of changes in gingivitis and depth of periodontal pocket and plaque index in the intervention and comparison group before and after chewing gum

Design

A clinical trial with an intervention and comparison group, with parallel, double-blind, randomized, phase 3 groups on 32 patients, a random number table was used for randomization.

Settings and conduct

This study is an interventional and double-blind clinical trial performed on patients with fixed orthodontics. The patients will randomly divided into two groups of intervention and comparison. Patients are selected voluntarily from among the patients referred to Hamadan Dental School of Medical Sciences. Plaque index and gingival index variables and periodontal pocket depth are measured in two groups of intervention and comparison at the time of admission, one month later and two months later. Participants and researchers in this study are blind. Randomization is performed using a table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria for people with a fixed treatment plan
Exclusion criteria for people with a history of systemic disease and dental caries and the use of any type of mouthwash and other medication or chewing gum during the research period

Intervention groups

The intervention group includes patients with gingivitis who receive chewing gum containing Crocus sativus petal extract. The control group includes patients with gingivitis who receive chewing gum without extract.

Main outcome variables

Gingival index; Probing depth; Plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150802023468N7**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

Registration date

2021-05-19, 1400/02/29

Registrant information

Name

Nazli Rabienejad

Name of organization / entity

Hamadan university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1059

Email address

n.rabinezhad@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of gum containing petal extract of crocus sativus on gingival inflammation in fixed orthodontic patients

Public title

Evaluation the effect of gum containing petal extract of crocus sativus on gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fixed orthodontic treatment plan

Exclusion criteria:

Systemic disease Tooth decay Use mouthwash or any other medication and gum during study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is block by size 4 blocks. Randomization is performed using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant and the investigator are both blind. Chewing gum packaging is similar to the comparison and intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Mardom street

City

Hamadan

Province

Hamadan

Postal code

6517736134

Approval date

2021-01-16, 1399/10/27

Ethics committee reference number

IR.UMSHA.REC.1399.878

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis: NOS desquamative hyperplastic simple marginal ulcerative

Primary outcomes

1

Description

gingival index

Timepoint

Baseline, one and two months after

Method of measurement

Inspection

2

Description

Probing depth

Timepoint

Baseline, one and two months after

Method of measurement

Periodontal probe

3

Description

Plaque index

Timepoint

Baseline, one and two months after

Method of measurement

Inspection

Secondary outcomes

1

Description

Analgesic effect

Timepoint

One day, two days and three days after starting chewing gum

Method of measurement

Visual Analogue Scale Questionnaire

Intervention groups

1

Description

Intervention group: The hydroalcoholic extract of *Crocus sativus* petal plant was extracted by soaking method and dried and concentrated by rotary distillation in vacuum, then gum containing *Crocus sativus* was produced in Mana and Dana factory with acceptable concentration. Patients use chewing gum twice a day for two months after each brushing.

Category

Treatment - Other

2

Description

Control group: Placebo chewing gum was produced in Mana and Dana factories without any extract. Patients use chewing gum twice a day for two months after each brushing.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Dental Faculty

Full name of responsible person

Nazli Rabinejad

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Hamadan Dental Faculty, Mardom street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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Hamadan University of Medical Sciences, Mardom street

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nasim Khademi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Nasim Khademi

Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Nasim Khademi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available