Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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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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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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
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Person responsible for updating data

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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
"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