Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Mouthwash Containing aqueous Extract of saffron on Gingival Indices of Patients With Generalized moderate to severe periodontitis

Protocol summary

Study aim
Clinical evaluation of the effect of mouthwash containing aqueous extract of saffron on gum index (PD, MGI, BI) in moderate to severe periodontitis patients

Design
Clinical trials with control group, with parallel groups, double-blind, randomized using random statistical data table, the sample size is 40 people in two groups of 20

Settings and conduct
From patients with moderate to generalized periodontitis referring to Shahid Sadoughi Dental School in Yazd, 40 patients are selected according to the inclusion and exclusion criteria.Patients are randomly divided into 2 groups of 20.The control group used chlorhexidine mouthwash and the intervention group using a mouthwash containing aqueous extract of saffron. A double-blind study (patient and researcher).

Participants/Inclusion and exclusion criteria
Entry condition: Patients with moderate to severe chronic periodontitis in more than 30% of the areas, the age group is over 35 years old with no systemic diseases and less than 65 years of age, patients with more than 16 natural teeth, patients with chronic periodontitis with loss of adhesion of more than 3 mm Non-arrival condition: Poor oral hygiene by patients

Intervention groups
Intervention group: patients with mouthwash aqueous extract of saffron Control group: Patients with chlorhexidine mouthwash

Main outcome variables
Periodontal Pocket Depth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190402043155N1**
Registration date: **2019-06-03, 1398/03/13**
Registration timing: **retrospective**

Last update: **2019-06-03, 1398/03/13**
Update count: **0**

Registration date
2019-06-03, 1398/03/13

Registrant information

Name
Vahid Herandi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3625 5881

Email address
herandi.vahid@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-03-06, 1397/12/15

Actual recruitment start date
2018-12-22, 1397/10/01

Actual recruitment end date
2019-03-16, 1397/12/25

Trial completion date
2019-04-21, 1398/02/01

Scientific title
Evaluation of the effect of Mouthwash Containing aqueous Extract of saffron on Gingival Indices of Patients With Generalized moderate to severe periodontitis

Public title
Evaluation of the effect of Mouthwash Containing aqueous Extract of saffron on Gingival Indices of Patients With Generalized moderate to severe periodontitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with moderate to severe chronic periodontitis in more than 30% of the areas Individuals over 35 years of age without systemic diseases and under 65 years of age due to the avoidance of age-related effects on periodontal disease Patients with more than 16 natural teeth Patients with chronic periodontitis with loss of adhesion of more than 3 mm and evidence of radio-graphic bone resorption
Exclusion criteria:
Poor oral hygiene by patients
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Use the random number table provided by the statistical software
Blinding (investigator's opinion)
Double blinded
Blinding description
Two types of mouthwashes in dark bottles (anti-light glass covers) are packaged and divided into two groups A and B by the pharmacist, which patients and dentist therapists do not know about the nature of mouthwashes until the end of the data collection.After analyzing data, the type of mouthwash is announced by the pharmacist.
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
Bahonar Square
City
Yazd
Province
Yazd
Postal code
8915173160
Approval date
2018-12-22, 1397/10/01
Ethics committee reference number
IR.SSU.REC.1397.169

Health conditions studied

1

Description of health condition studied
Chronic periodontitis
ICD-10 code
K05.3
ICD-10 code description
Chronic pericoronitis

Primary outcomes

1

Description
Pocket Probing Depth
Timepoint
The beginning of the study (before the start of the intervention) and 4 weeks after starting the mouthwash
Method of measurement
Periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients treated with mouthwash containing aqueous extract of saffron
Category
Treatment - Drugs

2

Description
Control group: Patients treated with chlorhexidine mouthwash
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Faculty of Dentistry
Full name of responsible person
Vahid Herandi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaii
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Vahid Herandi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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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