

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 radiographic 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Faculty of Dentistry

Full name of responsible person

Vahid Herandi

Street address

Imam Reza Blvd

City

Yazd

Province

Yazd

Postal code

8914815667

Phone

+98 35 3625 5881

Fax

+98 35 3625 0344

Email

pajoheshdentyazd@gmail.com

Web page address

<http://ssu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9138

Email

mmirzaei@ssu.ac.ir

Web page address

<https://ethic@ssu.ac.ir>

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

Street address

Imam Reza Blvd

City

Yazd

Province

Yazd

Postal code

8914815667

Phone

+98 35 3625 5881

Email

Herandi.vahid@yahoo.com

Person responsible for scientific 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

Street address

Imam Reza Blvd

City

Yazd

Province

Yazd

Postal code

8914815667

Phone

+98 356255881

Email

Herandi.vahid@yahoo.com

Person responsible for updating data

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

Others

Street address

Imam Reza Blvd

City

Yazd

Province

Yazd

Postal code

8914815667

Phone

+98 356255881

Email

Herandi.vahid@yahoo.com

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