

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of herbal mouthwash (pedicough) on plaque control and gingival inflammation in gingivitis patients

Protocol summary

Study aim

Clinical evaluation of the effect of pedicough mouthwash on plaque control and gingival inflammation in patients with gingivitis and also the introduction of a herbal mouthwash to reduce gingivitis parameters and improve plaque control

Design

The study is a parallel double blind study. Randomization and assignment of patients to each of the three groups is done by the ward nurse. Three mouthwashes are offered in the same package to 45 patients. Patients, administrator and student are not aware of the type of mouthwash. Randomization will be performed by sealed computer assisted files. The data will be analyzed by SPSS software version 17.

Settings and conduct

45 patients with generalized gingivitis, referred to the periodontology department of Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

This study will be performed on 45 patients with generalized gingivitis, referred to the periodontology department of Shiraz University of Medical Sciences. Examination of the clinical status and initial selection of the patients will be performed in the ward. In this study, smokers, pregnant women, patients with a history of medical problems that interfere with periodontal treatment, people who have done scaling and root planing in the past 3 months or have taken antibiotics in the past month will be excluded from the study.

Intervention groups

Individuals are randomly divided into three groups of fifteen. One group will be given chlorhexidine mouthwash, another group will receive a herbal mouthwash made from pedicough syrup, and the third group will receive a placebo mouthwash.

Main outcome variables

Gingival index (Loe and sillnes); Bleeding index (lenox); Plaque index (PI) (oleary)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211130053233N1**

Registration date: **2022-03-17, 1400/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-17, 1400/12/26**

Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

maedeh ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3823 2607

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maedeh1996gh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-05-19, 1401/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of herbal mouthwash (pedicough) on plaque control and gingival inflammation in gingivitis patients

Public title

Effect of Pedicough on gingival inflammation and oral hygiene

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with generalized marginal and papillary gingivitis

Exclusion criteria:

Smokers
Pregnancy
History of medical problems that interfere with periodontal treatment
People who have had SRP in the past 3 months, or who have taken antibiotics in the past month

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation in test and control groups will be randomly assigned to each patient by computer-generated random number table. The randomization codes will be stored in password-protected portable computers and enclosed in sequentially numbered, identical, sealed envelopes. The sealed envelopes will be opened in numerical order after scaling and root planing and before allocation of mouth washes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double blind. Randomization and assignment of patients to each of the three groups is done by the ward nurse, and the student who performs the scaling, examinations, and measurements is blind from the grouping. Also, three mouthwashes are offered to patients in three identical packages that patients, administrators and students are not aware of the type of the mouthwash.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiaz Dental School, Ghasroldasht Ghomabad Ave.

City

shiraz

Province

Fars

Postal code

719561578

Approval date

2022-02-18, 1400/11/29

Ethics committee reference number

IR.SUMS.DENTAL.REC.1400.079

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

Gingivitis (gingival inflammation)

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes**1****Description**

Lenox bleeding index : Evaluation of gingival bleeding

Timepoint

Before and after intervention

Method of measurement

williams probe

2**Description**

Oleary plaque index: evaluation of tooth surface plaque

Timepoint

Before and after intervention

Method of measurement

By disclosing tablets

3**Description**

Gingival index : Loe and Sillness

Timepoint

Before and after intervention

Method of measurement

Evaluation of gingival inflammation signs and bleeding

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving test mouth wash pedicough(by Dine factory).15 ml each time and twice a day for 2 minutes each time for 2 weeks, use this mouthwash (in the form of rotation in the mouth).

Category

Treatment - Drugs

2

Description

Intervention group: receiving chlorhexidine mouth wash(2% of Darobox Pharmaceutical Company).15 ml each time and twice a day for 2 minutes each time for 2 weeks, use this mouthwash (in the form of rotation in the mouth).

Category

Treatment - Drugs

3

Description

Control group: receiving placebo .Taken from the pedicough syrup (base prepared in Shiraz School of Pharmacy).15 ml each time and twice a day for 2 minutes each time for 2 weeks, use this mouthwash (in the form of rotation in the mouth).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dental School

Full name of responsible person

Dr Farein Kiani Yazdi

Street address

Shiraz Dental School, Ghasrodasht ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpour

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr Farin Kiani Yazdi

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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