Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of topical formulation (mouthwash) containing Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis efficiency in patients with gingivitis

Protocol summary

Summary

Objectives: Evaluation of topical formulation (mouthwash) containing Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis efficiency in patients with gingivitis. Design: randomized, double-blind, placebo-controlled, single center, second phase clinical trial. Study groups: patients with mild to moderate gingivitis. Sample size: 60 patients divided equally in the treatment group, placebo group and positive-control group. Inclusion criteria: patients with gingivitis; having at least 18 natural teeth; MGI scores between 1.3-2.75; MQH scores of at least 1.5. Exclusion criteria: requirement of antibiotic therapy for treatment of gingivitis; using antibiotics for at least 14 days before and after the study; using anti-inflammatory drugs during the study; using anticoagulation drugs during the study; using immunosuppressive drugs; patients under 18 or over 65; pregnancy and lactation. Intervention: a mouthwash containing the extract of Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis is used in patients with mild to moderate gingivitis. In the placebo group a similar mouthwash without the herbal extracts is used. In the positive-control group Chlorhexidine 0.2% mouthwash is used. This study is carried out in a 2 week period and the scores are evaluated each week by the dentist. Primary outcome variable: Modified Gingival Index (MGI). Secondary outcome variables: Gingival Bleeding Index (GBI); Modified Quigley- Hein Plaque Index (MQH).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070523078N1**
Registration date: **2015-08-31, 1394/06/09**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-08-31, 1394/06/09

Registrant information

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Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-09-01, 1394/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical formulation (mouthwash) containing Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis efficiency in patients with gingivitis

Public title

Effect of the extract of Rosmarinus officinalis, Zingiber

officinalis and Calendula officinalis on gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with gingivitis; having at least 18 natural teeth; MGI scores between 1.3-2.75; MQH scores of at least 1.5. Exclusion criteria: requirement of antibiotic therapy for treatment of gingivitis; using antibiotics for at least 14 days before and after the study; using anti-inflammatory drugs during the study; using anticoagulation drugs during the study; using immune-suppressive drugs; advanced gum diseases; patients under 18 or over 65; Sjogren's Syndrome; orthodontic disease; pregnancy and lactation.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee on Medical Research Ethics

Street address

Ghoraishy building, Daneshgah St.

City

Mashhad

Postal code

Approval date

2015-05-04, 1394/02/14

Ethics committee reference number

IR.MUMS.REC.1394.40

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Gingivitis (chronic)

Primary outcomes

1

Description

Modified Gingival Index (MGI)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Observation and Evaluation

Secondary outcomes

1

Description

Gingival Bleeding Index (GBI)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Observation and evaluation

2

Description

Modified Quigley- Hein Plaque Index (MQH)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Observation and evaluation

Intervention groups

1

Description

Herbal mouthwash: Mouthwash formulation of Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis's extract, for each patient 10 milliliters twice a day for two weeks.

Category

Treatment - Drugs

2

Description

Placebo mouthwash: Mouthwash formulation similar to treatment group, but without the extracts of Zingiber officinalis, Rosmarinus officinalis and Calendula officinalis, for each patient 10 milliliters twice a day for

two weeks.

Category

Treatment - Drugs

3

Description

Positive-control: Chlorhexidine 0.2 % mouthwash, for each patient 10 milliliters twice a day for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pharmaceutical Sciences Research Center

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Pharm D student

Other areas of specialty/work

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Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty