# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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**

**Name**
Saman Mahyari
**Name of organization / entity**
Mashhad University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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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**

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**Position**

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## 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*