

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical effect of hyssopus mouthwash on periodontal indexes compare with chlorhexidine; A Double-Blind, Randomized Clinical Trial

Protocol summary

Study aim

Clinical effect of Hyssop Herbal mouth wash on periodontal indexes compare with chlorhexidine

Design

The present study is a double-blind randomized clinical trial (simple randomization). This clinical trial has a control group (treated with chlorhexidine), an intervention group (treated with hyssop mouthwash) and a placebo on sixty patients.

Settings and conduct

The present study is a double-blind randomized clinical trial (simple random sampling) that is performed on patients referred to Sari Dental School in 1399. Treatment steps were explained to all patients. Clinical parameters including pigment index, plaque index, gingival index and bleeding during probe on Ramfjord teeth, which include central teeth and first left upper and lower right premolars and first right upper and lower left molars are determined. Three of these indicators will be re-evaluated to evaluate the effects of treatment. Patients are instructed to gargle 5 ml of mouthwash twice a day for 30 seconds and use these mouthwashes for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having 12 incisors; mild to moderate gingivitis and absence of pocket and loss of attachment; absence of color in the tooth and the lack of allergy to chlorhexidine and Origanum vulgare; non-use of intraoral removable prosthesis; history of antibiotic use 3 last month and no smoking. Exclusion criteria: Pregnancy, breastfeeding, underlying diseases such as cancer, autoimmune diseases, diabetes, etc.

Intervention groups

The intervention group includes the group treated with Hyssop Herbal mouthwash. Intervention group 2 includes the group treated with chlorhexidine mouthwash. The control group includes the placebo group.

Main outcome variables

Dental plaque; gingivitis ; Bleeding gums; Staining of

teeth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031242N2**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Emran Habibi

Name of organization / entity

Mazandaran University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 11 3354 3761

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical effect of hyssopus mouthwash on periodontal indexes compare with chlorhexidine; A Double-Blind, Randomized Clinical Trial

Public title

Clinical effect of Hyssop Herbal mouthwash

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having 12 incisors mild to moderate gingivitis and absence of pocket and loss of attachment absence of color in the tooth and the lack of allergy to chlorhexidine and Hyssop non-use of intraoral removable prosthesis history of antibiotic use 3 last month no smoking

Exclusion criteria:

pregnancy Breastfeeding Underlying diseases such as cancer, autoimmune disease, diabetes, etc.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization was performed by simple randomization. sixty codes were defined with the help of a random table and mouthwashes were coded and mouthwashes (hyssopus, chlorhexidine and placebo) in one-shaped, dark-colored and sealed bottles according to the codes defined in Random is provided to patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two groups of patients receiving mouthwash (placebo, chlorhexidine and hyssopus) and a clinical caregiver (dentist) were kept blind in the study groups. People will not know how to dispense mouthwash, and mouthwashes are available to patients in dark bottles with the same color, shape, and sealed according to randomly defined codes. The tools and ingredients needed to make the placebo will be exactly the same as the hyssopus mouthwash, except that the only active ingredient in the extract is removed from the placebo mouthwash.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mazandaran University of Medical Sciences

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Moalem Ave.

City

sari

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Mazandaran

Postal code

4847193698

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.MAZUMS.REC.1399.568

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

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

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

Gingival inflammation

Timepoint

before and after treatment

Method of measurement

Observation

Secondary outcomes**1****Description**

Oral allergy

Timepoint

During the study, and then

Method of measurement

Observation

2**Description**

Staining of teeth

Timepoint

before and after treatment
Method of measurement
Observation

3

Description
Gingival bleeding

Timepoint
before and after treatment

Method of measurement
Observation

4

Description
The clinical characteristics of plaque

Timepoint
before and after treatment

Method of measurement
Observation

Intervention groups

1

Description
Intervention group: 10 ml Hyssop Herbal mouthwash 2 times a day for 2weeks

Category
Treatment - Drugs

2

Description
Intervention group: 10 ml Chlorhexidine mouthwash 2 times a day for 2weeks

Category
Treatment - Drugs

3

Description
control group: 10 ml placebo mouthwash 2 times a day for 2weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Private Dental clinic

Full name of responsible person
Hadis Ehsani

Street address
Sari city, Khazar boulevard, former medical school, Toobi specialized and sub-specialized clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Ahmad Ali Enayati

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Emran Habibi

Position
Ph.D. Assistant Professor

Latest degree
Ph.D.

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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