Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 group1includes the group treated with Hyssop Herbalmouthwash. 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)
Phone
+98 11 3354 3761
Email address
ehabibi@mazums.ac.ir

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 Sceinces
Street address
Moalem Ave.
City
sari
Province
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
City
sari
Province
Mazandaran
Postal code
4847193698
Phone
+98 11 3324 0003
Email
ehabibi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Mazandaran University of Medical Sciences, Moalen Avenue
City
sari
Province
Mazandaran
Postal code
4847193698
Phone
+98 11 3354 3695
Email
ehabibi@mazums.ac.ir
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.
Other areas of specialty/work

Medical Pharmacy
Street address
School of Pharmacy, Farah Abad
City
sari
Province
Mazandaran
Postal code
4847193698
Phone
+98 11 3354 3695
Email
emrapharm@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Emran Habibi
Position
Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Farah Abad
City
sari
Province
Mazandaran
Postal code
4847193698
Phone
+98 11 3354 3695
Email
emrapharm@yahoo.com

Person responsible for updating data

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.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Farah Abad
City
sari
Province
Mazandaran
Postal code
4847193698
Phone
+98 11 3354 3695
Email
emrapharm@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