

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Clinical effect of Aloysia citriodora mouth wash on plaque-induced gingivitis compare with chlorhexidine

Protocol summary

Study aim

Clinical effect of Aloysia citriodora mouth wash on plaque-induced gingivitis compare with chlorhexidine

Design

In this phase 3 Clinical Trial, after considering the entry and exit criteria, the study subjects are randomly divided into three groups using random allocation software. Considering the total volume of samples, 72 people, there are 24 samples in each group.

Settings and conduct

Sari dentistry University. This clinical Trial is double blinded so the researcher and the participants have no information about the type of mouthwashes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people who have plaque induced generalized chronic gingivitis; not having systemic disease; not using antibiotics in last 3 months; not having known allergies to lippia citriodora plant; not using drugs affecting periodontum directly. Exclusion criteria: smoking; pregnant women; those who have received periodontal treatment in last 3 months.

Intervention groups

The first group will receive Lippia citriodora mouthwash, The second group will receive chlorhexidine mouthwash and placebo will be given to third group.

Main outcome variables

Gingival index - plaque index - bleeding on probing- mouthwash rinse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190117042392N1**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **prospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

Registration date

2019-02-26, 1397/12/07

Registrant information

Name

Dorsa Giahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 3228

Email address

dorsagiahi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical effect of Aloysia citriodora mouth wash on plaque-induced gingivitis compare with chlorhexidine

Public title

Clinical effect of Aloysia citriodora mouth wash on plaque-induced gingivitis compare with chlorhexidine

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

people who have plaque induced generalized chronic gingivitis. not having systemic disease. not using antibiotics in last 3 months. not having known allergies to lippia cotriodora plant . not using drugs affecting periodontum directly.

Exclusion criteria:

smokers pregnant women those who have received periodontal treatment in last 3 months.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

After considering entry and exit criteria, Assigning samples to three groups by the means of blocking method will be done. So there will be 12 blocks of 6 with the use of Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the participant are not aware of the type of mouthwashes and do not know in which group participants are assigned.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran university of medical sciences

Street address

Khazar Blvd. Sea road 17 km. Mazandaran university of medical sciences. Sari city

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.MAZUMS.REC.1397.273

Health conditions studied

1

Description of health condition studied

Plaque induced gingivitis

ICD-10 code

k05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Changes in gingival index, plaque index and bleeding upon probing

Timepoint

At the beginning of the study, first and third weeks

Method of measurement

Observation and probing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: lippia citriodora mouthwash made from its extract will be rinsed twice a day each time 30 seconds 10 ml for 2 weeks. The patient will be trained not to eat or drink 30 minutes after using the mouthwash. Correct method of brushing and oral hygiene will be trained to patients.

Category

Treatment - Drugs

2

Description

Intervention group two: normal saline as placebo will be given to this group in dark bottles. patients will be instructed to rinse the mouthwash twice a day each time 30 seconds 10 ml for 2 weeks. The patient will be instructed not to eat or drink 30 minutes after the use of mouthwash. Correct form of brushing and oral hygiene will be instructed to patients.

Category

Treatment - Drugs

3

Description

Control group: chlorhexidine mouthwash 0.2% (Behsa

productions) will be poured in dark bottles and given to patients. Patients will be instructed to rinse the mouthwash twice a day each time 30 seconds 10 ml for 2 weeks. Patient will be instructed not to eat or drink 30 minutes after the use of mouthwash. Correct form of brushing and oral hygiene will be instructed to patients.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sari Dental School

Full name of responsible person

Hodis Ehsani

Street address

Sari Dental Clinic, Khazar Blvd.

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

hodis_ehsani@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Khazar Blvd. dental school and clinic of Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

dorsagiahi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sari 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

Dr. Hodis Ehsani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Khazar Blvd. Sari dental school

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4014

Email

hodisehsani@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Hodis Ehsani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Khazar Blvd. Sari dental school

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

hodis_ehsani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Hodis Ehsani

Position

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Latest degree

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Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

hodis_ehsani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the complete information of patients can be accessed in anytime after protocol . letter of satisfaction and ethic codes are written in the project.

When the data will become available and for how long

after the results

To whom data/document is available

researchers

Under which criteria data/document could be used

researchers who want to do experimental studies related to this subject

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

after sending Email and descriptions about his/her work can expect the answer few weeks later.

Comments