

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A survey efficacy of Terminalia chebula and Commiphora opobalsamum oral mouth wash on denture stomatitis

Protocol summary

Study aim

A survey efficacy of Terminalia chebula and Commiphora opobalsamum oral mouth wash on denture stomatitis

Design

The clinical trial has a control group, with parallel, double-blind, randomized groups

Settings and conduct

This research is a double-blind clinical trial, which was performed on 50 patients with a denture stomatitis (this number of patients were selected based on previous studies and without the sample size formula). After clinical examination and confirmation of the type 2 disease and fill consent form, patients are included in the research. At the beginning, demographic information about age, gender, duration of use of the denture in time of sleep, the denture cleaning method and record the number of times cleaning. The patients were randomly divided into two groups of treatment 1) Herbal mouthwash containing Halileh and belsan.2) Mouthwash with Protact.

Participants/Inclusion and exclusion criteria

This research is a double blind clinical trial, which was performed on 50 patients with a steomatitis (this number of patients based on previous studies and without formulas of sample size). Patients who have a history of using antifungal, antibiotic and corticosteroid drugs in a recent month or are diagnosed with immunopressing disease, as well as those who are allergic to Halileh and, and protact mouthwash, have rodent muscles and cannot be used to turn mouthwash in the mouth from the study removed.

Intervention groups

The study consisted of two groups of control and drug recipient. The intervention group received the drug-containing mouthwash and the control group received the Protact Mouth wash.

Main outcome variables

Diameter of erythema Recovery time Herbal mouthwash containing halile and Belsan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130911014630N8**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **retrospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Mohammad Azadbakht

Name of organization / entity

Mazandaran University of Medical Scinecee

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3728

Email address

mazadbakht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-10, 1398/08/19

Expected recruitment end date

2019-12-10, 1398/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey efficacy of Terminalia chebula and Commiphora opobalsamum oral mouth wash on denture stomatitis

Public title

A survey efficacy of Terminalia chebula and Commiphora opobalsamum oral mouth wash on denture stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patient with denture stomatitis

Exclusion criteria:

Patients who have a history of using antifungal, antibiotic and corticosteroid drugs, and immunosuppress drugs in a recent month patient are infected with immunosuppression disease who are allergic to Halileh or protact mouthwash patient who have Alzheimer's, disorders Rodent muscles and cannot rotate the mouthwash in the mouth are eliminated from the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

The mouthwash is given in containers similar to the size, taste and smell of the patients

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher, patient, and specialist physician are unaware of the type of product.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mazandaran University of Medical Science research ethics committee

Street address

Darya Street

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2019-05-09, 1398/02/19

Ethics committee reference number

ir.mazums.rec.1398.1387

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

denture stomatitis

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

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

diameter of erythema

Timepoint

end of the first and second week

Method of measurement

diameter of erythema by caliper

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

recovery duration

Timepoint

first and second week

Method of measurement

The duration of the improvements in erythema diameter by caliper

Intervention groups**1****Description**

Control group: Patients are asked to gargle 20 drops of Protact 2 times a day (morning and afternoon) and refrain from eating and drinking for half an hour. Do not use denture during sleep and place it in a 10: 1 ratio of water and vinegar.

Category

Prevention

2

Description

Intervention group: Patients are asked to gargle 20 drops of mouthwash twice a day (morning and afternoon) and refrain from eating and drinking for half an hour. Do not use it during sleep and place it in a container of water and vinegar at a ratio of 10 to 1 and replace your denture. The erythematous area is examined at the end of the first and second weeks and recovery is recorded in the form of denture stomatitis (type 2 to 1 conversion or complete remission).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuoshirvani Geriatric Center

Full name of responsible person

Dr Mohamad Azadbakht

Street address

Hamzekola

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4664117886

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Emran Habibi

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Darya street

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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

70

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 Mohamad Azadbakht

Position

Professor of University

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Mazandaran University of Medical Sciences

Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Maryam Mirdar Mansouri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Respecting patients privacy

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Because of patient privacy, their information is kept confidential, but the method of study and statistical data are coded to be published

When the data will become available and for how long

one year

To whom data/document is available

Advisor and researcher Supervisor

Under which criteria data/document could be used

If you expand the study and allow teachers to help

From where data/document is obtainable

Professor of University

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

Visiting University and professor of University

Comments