Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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 immunosupress 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 Sciense 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

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Hamzekola

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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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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

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Latest degree
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Medical Pharmacy

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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