

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparing the antifungal effect of Ganoderma gel and Clotrimazole gel in patients with denture stomatitis

Protocol summary

Study aim

To compare the effect of Clotrimazol gel and Ganoderma gel in symptom reducing and lesion improvement among patients with denture osteomatitis.

Design

Clinical trial with control group, parallel groups, blinded postoperative care and outcome assessment, randomized, on 60 patients. randomization with random numbers table.

Settings and conduct

Research will be accomplished in oral disease section of Isfahan Dental Faculty in 2019-2020 under the observation of a specialist. Double blinding will be applied so that patients and researcher won't realize the type of drug have been given.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Users of acrylic complete removable denture in maxilla who shows signs of type 1 or 2 denture stomatitis. Non-inclusion criteria: history of Anti fungal, Anti bacterial, Corticosteroid drugs usage in last month.

Intervention groups

Intervention group : will be given 5% Ganoderma gel.
Control group: will be given 1% Clotrimazol gel. All patients will be asked to do oral and denture hygiene after every meal then clean the tissue side of denture with 12% clorohegzidine and use 5 cm of gel inside denture and put it back inside the mouth.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046685N2**

Registration date: **2020-07-06, 1399/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**

Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Fahimeh Pakravan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3436 8793

Email address

pakravan@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the antifungal effect of Ganoderma gel and Clotrimazole gel in patients with denture stomatitis

Public title

Evaluation of antifungal effect of Ganoderma in denture stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Users of acrylic complete removable denture in maxilla who shows signs of type 1 or 2 denture stomatitis.

Exclusion criteria:

History of Anti fungal, Anti bacterial, Corticosteroid drugs usage in last month Hypersensitivity to Ganoderma or Clotrimazole Immune suppression disorders Alzheimer disease Neuromuscular disease Mental disorders and lack of cooperation Chemotherapy or radiotherapy of head and neck in present or past

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is simple random sampling. Randomization unit: individual. Randomization tool: Random number table. Among patients suffering from Denture stomatitis referred to Isfahan University of Medical Sciences, 60 patients who have been examined and met the eligibility criteria will enter the study and a number will be assigned to every patient. Then they will be divided into two groups using block randomization (block size=30) in the random allocation service software. For allocation concealment, sealed coded boxes with same size and weight will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients know about drugs used in the research but they don't know which treatment they will be given. The result evaluator clinically observes patients only on follow up sessions. Also the researcher doesn't know about randomization and type of drug each patient have received because the clinical observant is only responsible for drug distribution.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Department of oral medicine; Faculty of Dentistry; Isfahan University of Medical Sciences; Soffeh boulevard

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.796

Health conditions studied

1

Description of health condition studied

Denture ostomatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Before starting research, 7, 14 days afters using drug

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients using 5% Ganoderma 3 times a day by putting 5 cm of gel inside the denture. Mushroom has been bought then it has been extracted by Pharmacognosy section of Isfahan University of Medical Sciences and has been used to produce the gel.

Category

Treatment - Drugs

2

Description

Control group: patients using 1% Clotrimazole 3 times a day by putting 5 cm of gel inside the denture. Powder of Clotrimazole has been bought from Raha company then Pharmaceutics section of Isfahan university of medical

science has made the gel.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of oral medicine; Faculty of Dentistry;
Isfahan University of Medical Sciences

Full name of responsible person

Fahimeh Pakravan

Street address

Soffeh Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fahimeh Pakravan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fahimeh Pakravan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Email

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Negin Ghahremani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

Commitment to the principle of confidentiality of the patient's record

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only information such as main consequence or the like can be shared.

When the data will become available and for how long

Access to the results immediately after publication

To whom data/document is available

Open access

Under which criteria data/document could be used

Access to data is possible only after formal permission from corresponding author

From where data/document is obtainable

Corresponding author

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

Formal letter or email

Comments