

# 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

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Soffeh Boulevard

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8117891389

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pakravan@dnt.mui.ac.ir

**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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Department of oral medicine; Faculty of Dentistry;  
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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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## 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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Milad dormitory, Hezarherib Ave

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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**