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# A comparative study between the antifungal activity of curcumin and nystatin in denture stomatitis (randomized controlled trial)

**Submission date**
07/08/2023

**Recruitment status**
No longer recruiting

**Registration date**
24/08/2023

**Overall study status**
Completed

**Last Edited**
02/10/2023

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Denture stomatitis is an inflammation of the oral mucosa caused by Candida infections. This study will compare the effectiveness of curcumin suspension and nystatin suspension in patients for the treatment of denture stomatitis.

Who can participate?
Patients who have been diagnosed with denture stomatitis

What does the study involve?
The patients will be randomly assigned to one of two groups:

Group I: The patients in this group will be treated with curcumin suspension three times a day for 14 days
Group II: The patients in this group will be treated with nystatin suspension three times a day for 14 days

The effectiveness of the two treatments will be assessed by three measures:
1. Healing: The patients' oral mucosa will be evaluated using a scale of oral mucositis at 7 and 14 days after treatment
2. Taste acceptability: The patients will be asked to rate the taste of the two treatments on a hedonic scale on the 14th day after treatment
3. Laboratory assessment: The number of fungal colonies will be counted before and after treatment

What are the possible benefits and risks of participating?
This study will increase the trend towards the use of natural materials to reduce the drug interactions of traditional antifungal drugs. The curcumin plant has been chosen because of its ease of availability and its scientifically proven antifungal properties in many studies.

This study will provide valuable information on the effectiveness of curcumin suspension and nystatin suspension in the treatment of denture stomatitis. The results of this study could lead to the development of new and more effective treatments for this condition.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
Match 2022 to March 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Shahed Kuraitby, shahed.kuraitby@damascusuniversity.edu.sy (Syria)

### Study website
http://www.damascusuniversity.edu.sy/

# Contact information

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Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
3211

## Study information

### Scientific Title
In patients with denture stomatitis, is there evidence to suggest that curcumin gives better clinical and laboratory antifungal results than nystatin?

### Study objectives
1. Does curcumin suspension have efficacy in treating denture stomatitis?
2. Does curcumin suspension outperform traditional fungal drugs?
3. Does curcumin suspension affect the number of fungal colonies?

### Ethics approval required
Ethics approval required

### Ethics approval(s)

Approved 24/07/2022, Scientific Research Council at the Faculty of Dentistry at Damascus University (Mazzeh Street, Damascus city, -, Syria; +963112119809; dl.srd@damascusuniversity.edu.sy), ref: 3211

## Study design
Randomized controlled clinical study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Dental clinic, Laboratory

## Study type(s)
Treatment, Efficacy

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Denture stomatitis

## Interventions
Patients who are informally and clinically positive for denture stomatitis will be enrolled in this study.

The patients were divided into two groups:
Group I: Curcumin suspension three times a day, 15 ml per dose, for 14 days
Group II: Nystatin suspension 100,000 UN three times a day for 14 days

The patients were assigned to the two groups in a sequential manner, with the first patient receiving treatment with curcumin suspension, the second patient receiving treatment with nystatin suspension, and so on.

## Intervention Type
Drug

## Pharmaceutical study type(s)
Not Applicable

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Curcumin suspension, nystatin suspension

## Primary outcome measure

1. Healing measured using a scale of oral mucositis at 7 and 14 days
2. Taste acceptability measured using a Hedonic scale on the day 14 since treatment began

### Secondary outcome measures
Laboratory assessment measured using the decrease in the number of fungal colonies taken before the commencement of processing and on day 14 after the completion of processing

### Overall study start date
26/03/2022

### Completion date
01/03/2024

## Eligibility

### Key inclusion criteria
1. Adult patients
2. Male or female
3. Who use dental devices
4. Clinically and informally diagnosed with denture stomatitis

### Participant type(s)
Patient, Learner/student

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
30 patients divided into two groups so that each group includes 15 patient

### Key exclusion criteria
1. Pregnant or nursing women
2. Patients treated with any antifungal medication over the past two weeks
3. Patients with any allergic reactions to studied substances
4. Patients with HIV
5. Immunosuppressed patients

### Date of first enrolment
03/10/2022

### Date of final enrolment

01/12/2023

# Locations

**Countries of recruitment**
Syria

**Study participating centre**
**Department of Oral Medicine at the Faculty of Dentistry at Damascus University**
Mazzeh Street
Damascus
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# Sponsor information

**Organisation**
Damascus University

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Scientific Research Council
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**Sponsor type**
University/education

**Website**
http://www.damascusuniversity.edu.sy

**ROR**
https://ror.org/03m098d13

# Funder(s)

**Funder type**
University/education

**Funder Name**
Damascus University

**Alternative Name(s)**
University of Damascus, , DU

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Syria

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
01/01/2025

**Individual participant data (IPD) sharing plan**
The datasets generated and analyzed during the current study will be available on request from Shahed kuraitby (shahed.kuraitby@damascusuniversity.edu.sy)

**IPD sharing plan summary**
Available on request