

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/08/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/10/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Type(s)
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 (Mazze 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

Mazzeah Street

Damascus

Syria

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Sponsor information

Organisation

Damascus University

Sponsor details

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