

Mouth sores from dentures in older adults in the UAE: how common are they and what causes them

Submission date 17/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/12/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Denture stomatitis refers to sores that form on the soft tissues of the mouth, often affecting people who wear removable dentures. These sores can appear as small, isolated sore spots, larger red patches, or even areas of soft tissue growth, commonly on the roof of the mouth. The goal of this study is to find out how common denture stomatitis is among older adults in the UAE who wear removable dentures. In addition, the study will look at which factors may lead to the development or worsening of these sores. By better understanding this condition, we hope to help health officials plan ways to prevent and manage it more effectively.

Who can participate?

Men and women who are 50 years of age or older, who have been wearing removable dentures for at least 1 year

What does the study involve?

If you choose to participate, you will have a standard dental examination of your mouth using a simple mouth mirror and a dental explorer. You will also be asked to complete a brief questionnaire about your general health, dental and denture history, and oral hygiene habits.

What are the possible benefits and risks of participating?

There are no known risks to participating in this study. Although you will not receive any direct personal benefit, the information we gather will be valuable to the community. It will help us understand how common these sores are and what causes them, and in turn, assist government health agencies in developing plans to manage and prevent this condition in the future.

Where is the study run from?

Ras Al Khaimah Specialized Dental Center (United Arab Emirates)

When is the study starting and how long is it expected to run for?

May 2023 to June 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nabeel Alsabeeha, nabeel.galeb@ehs.gov.ae

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MOHAP/DXB-REC/ J.J.J /No.78 / 2023

Study information

Scientific Title

Denture stomatitis in older adult population in the United Arab Emirates: a cross-sectional study on prevalence and associated risk factors

Study objectives

What is the prevalence rate of denture stomatitis among older adult denture wearers in the UAE, and what are its associated risk factors?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/06/2023, Ministry of Health and Prevention Research Ethics Committee (Muhaisna 2, SMBZ Road, Dubai, PO Box 3071, United Arab Emirates; +971 (0)8001111; info@mohap.gov.ae), ref: MOHAP/DXB-REC/ J.J.J /No.78 / 2023

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Dental clinic

Study type(s)

Diagnostic, Screening

Participant information sheet

Not available in web format, please use contact details to request a participants information sheet.

Health condition(s) or problem(s) studied

Denture stomatitis

Interventions

A sample of older adults (aged >50 years) will be clinically examined for the presence of denture stomatitis. Additionally, each participant will be required to fill up a structured questionnaire to collect relevant information including demographic data, medical and dental histories, habits, and denture history, usage and hygiene. The participant's existing denture will also be examined to evaluate its quality based on standard criteria.

Intervention Type

Other

Primary outcome measure

The prevalence rate of denture stomatitis in the target population, determined by direct clinical examination to identify the affected individual and the type of condition. Measured at a single timepoint for each participant.

Secondary outcome measures

Risk factors for denture stomatitis determined from medical history and structured questionnaires. Measured at a single timepoint for each participant.

Overall study start date

01/05/2023

Completion date

30/06/2025

Eligibility

Key inclusion criteria

1. Male or female patients 50 years and above
2. Wearing removable partial and/or complete dentures for at least 1 year
3. Willing to comply with research visits and follow-up as needed
4. Able to provide informed consent

Participant type(s)

Patient, Service user

Age group

Senior

Lower age limit

50 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

500

Key exclusion criteria

1. Patients with denture use of less than 1 year
2. Patients under radiotherapy or immunosuppressive medications
3. Patients with mental illness or drug abuse
4. Patients unable to provide informed consent

Date of first enrolment

23/12/2024

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

United Arab Emirates

Study participating centre

RAK Specialized Dental Center
18 Al Mashfa Street, Al Juwais
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PO Box 3071

Sponsor information

Organisation

Ministry of Health and Prevention

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in peer reviewed journal towards the end of 2025, once results collected, analyzed, and manuscript drafted and approved by authors.

Intention to publish date

01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are not expected to be made available due to data protection regulations.

IPD sharing plan summary

Not expected to be made available