

Investigating some of the oral manifestations associated with neutropenia - a clinical cross-sectional study

Submission date 11/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/03/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A lower number than usual of certain white blood cells (neutrophils) is termed neutropenia. Neutrophils are part of the immune system and neutropenia has many possible causes, either congenital or acquired, and chemotherapy is the most common. Neutropenia has a great effect on the oral cavity. Therefore, oral lesions and periodontal diseases can take the form of ulcers, infections, mucositis, gingivitis, and periodontitis. In addition, neutropenia may reduce the quality of life of these patients. This study aims to investigate the oral manifestations associated with chemotherapy-induced neutropenia in patients with hematological malignancies, to evaluate the role of neutropenia in the development of periodontal diseases and quality of life comparison between the neutropenic group and the non-neutropenic group.

Who can participate?

Patients with hematological malignancies undergoing chemotherapy

What does the study involve?

The study is an observational study that involves only a clinical examination after 2 weeks of starting a new chemotherapy course, in addition to a questionnaire about the patient's quality of life.

What are the possible benefits and risks of participating?

The benefits of this study are the early diagnosis of oral and periodontal lesions and receiving the appropriate treatment when needed, and there are no risks as no procedures are required.

Where is the study run from?

Damascus University (Syria)

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

January 2021 to January 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Fatima AlZahraa Al Beesh, fatimaalzahraa.albeesh@damascusuniversity.edu.sy

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Are patients undergoing chemotherapy who develop chemotherapy-induced neutropenia at greater risk for having oral lesions and periodontal diseases compared with patients without chemotherapy-induced neutropenia?

Study objectives

1. Neutropenia leads to changes in the oral mucosa and the appearance of some oral lesions
2. Neutropenia affects the periodontium and leads to pathological changes
3. Neutropenia affects and decreases the patient's quality of life

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/09/2021, The Scientific Research Committee of the Faculty of Dentistry of Damascus University (Faculty of Dentistry, Damascus University, Damascus City, 00963, Syria; +9631133923192 ; info@damascusuniversity.edu.sy), ref: 154

Study design

Cross-sectional clinical observational study

Primary study design

Observational

Study type(s)

Quality of life, Screening

Health condition(s) or problem(s) studied

Oral manifestations associated with neutropenia in patients with hematological malignancies undergoing chemotherapy

Interventions

The study sample consists of 50 patients divided into two groups as follows: the first group includes the hematological malignancies patients with chemotherapy-induced neutropenia (25 patients), and the second group includes the hematological malignancies patients without chemotherapy-induced neutropenia (25 patients). The patient is included in one of these groups depending on the absolute neutrophils count (ANC), after which a clinical dental examination is performed looking for the presence of oral lesions and periodontal diseases. In addition, a questionnaire is answered by patients to assess their quality of life.

The patient is observed after 2 weeks from the beginning of the chemotherapy course, and no follow-up is required.

Intervention Type

Other

Primary outcome(s)

1. Oral manifestations measured using clinical and visual diagnosis at a single timepoint
2. Periodontal diseases measured using clinical and visual diagnosis at a single timepoint
3. Quality of life measured using a questionnaire that concentrates on different aspects of life as a result of neutropenia/chemotherapy at a single timepoint

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

12/01/2023

Eligibility

Key inclusion criteria

First group (patients with chemotherapy-induced neutropenia):

1. Patients diagnosed with hematological malignancy
2. Patients who received at least one cycle of chemotherapy
3. Patients developing neutropenia after chemotherapy, with an absolute neutrophil count (ANC) less than $1.5 \times 10^9/L$

Second group (patients without chemotherapy-induced neutropenia):

1. Patients diagnosed with hematological malignancy
2. The patient has received at least one cycle of chemotherapy
3. The patient does not present with post-chemotherapy neutropenia, and has an ANC greater than $1.5 \times 10^9/L$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Patients receive radiation therapy as part of their treatment
2. The patient has been diagnosed with oral cancer
3. The patient is diagnosed with a non-hematological malignancy
4. The patient is diagnosed with diabetes

Date of first enrolment

24/10/2021

Date of final enrolment

31/08/2022

Locations**Countries of recruitment**

Syria

Study participating centre

Al-Bairouni University Hospital

Harasta

Damascus Countryside

Syria

00963

Study participating centre

Al-Assad University Hospital

Damascus

Damascus

Syria

00963

Study participating centre

University of Damascus,

Faculty of Dentistry

Damascus

Syria
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Sponsor information

Organisation

Damascus University

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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Fatima ALZahraa Al Beesh (fatimaalzahraaalbeesh@gmail.com). Consent from participants was required and obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/03/2025	18/03/2025	Yes	No