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

Submission date
11/08/2023

Recruitment status
No longer recruiting

Registration date
06/09/2023

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life, Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
13/01/2021

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 x 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 x 10^9/L

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
50

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,
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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 and peer-reviewed journal

Intention to publish date
17/01/2024

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