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Evaluation of the efficiency of photobiomodulation in the prevention of oral mucositis in chemotherapy-treated cancer patients

Submission date
20/07/2023

Recruitment status
No longer recruiting

Registration date
24/07/2023

Overall study status
Completed

Last Edited
07/02/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Oral mucositis is a common and extremely painful side effect experienced by cancer patients undergoing non-surgical treatments like chemotherapy or hematopoietic stem cell transplantation. The severity of oral mucositis varies depending on the type of treatment and cancer, with higher rates seen in head and neck cancer patients receiving both radiotherapy and chemotherapy. Currently, there are no effective treatments or established guidelines for preventing oral mucositis caused by anticancer chemotherapy. This lack of effective prevention negatively impacts patients' quality of life, prognosis, and care requirements. The best approach is to intervene preventively before lesions develop. Once the lesions do appear, they become more complicated due to the clinical problems they cause, impaired healing from the overall weakness caused by chemotherapy, and the risk of secondary infection. In summary, oral mucositis is a significant challenge in cancer treatment, but early preventive intervention is the most effective way to manage it and improve patients' well-being.

Who can participate?
Adults aged 25 to 65 years old with solid tumors who are undergoing chemotherapy for the first time with the risk of mucositis

What does the study involve?
This study aims to compare the effects of oral mucosal preconditioning by photobiomodulation therapy using a 650 nm diode laser alone or in combination with a 980 nm diode laser in preventing oral mucositis in cancer patients who will undergo chemotherapy for the first time.

What are the possible benefits and risks of participating?
Preconditioning with photobiomodulation is expected to provide desirable results in the prevention of oral mucositis without any side effects. It is expected to improve patient's quality of life by preventing them from the consequences of oral mucositis, such as pain, secondary infections, difficulty speaking, difficulty eating, and others.

Several studies have evaluated the effectiveness of photobiomodulation therapy in the prevention of oral mucositis in patients undergoing hematopoietic stem cell transplantation, and head and neck cancer patients undergoing radiotherapy, all of which showed positive results without any side effects, while studies in cancer patients who underwent chemotherapy are still limited. Therefore, this treatment is expected to provide desirable results in the prevention of oral mucositis without side effects.

Where is the study run from?
Al-Baironi University Hospital (Syria)

When is the study starting and how long is it expected to run for?
21/7/2023 and 18/1/2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Marwa Khalil, marwa.khalil@damascusuniversity.edu.sy (Syria)

Contact information

Type(s)
Scientific

Contact name
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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
Clinical and laboratory evaluation of the efficiency of preconditioning with photobiomodulation in preventing chemotherapy-induced oral mucositis

Study objectives
Photobiomodulation therapy is able to prevent chemotherapy-induced oral mucositis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/01/2023, Scientific Research Council at Damascus University (Damascus University, Damascus, 00963, Syria; +963 11 33923000; president@damasuniv.edu.sy), ref: 2027

Study design
Prospective randomized controlled double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Hospital, Laboratory

Study type(s)
Prevention, Quality of life

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
Prevention of oral mucositis in chemotherapy-treated cancer patients

Interventions
After achieving acceptance criteria, randomization will be performed using the online software www.graphpad.com/quickcalcs/randomize1.cfm.
• Group 1: Cancer patients who will receive basic oral care instructions before undergoing chemotherapy.
• Group 2: Cancer patients who will receive basic oral care instruction in addition to intraoral 650 nm laser diode photobiomodulation therapy prior to undergoing chemotherapy.
• Group 3: Cancer patients who will receive basic oral care instruction as well as intraoral photobiomodulation therapy using a 650 nm laser diode; and 980 nm extraoral before undergoing chemotherapy.

Intervention Type
Device

Pharmaceutical study type(s)

Not Applicable

Phase
Phase III

Drug/device/biological/vaccine name(s)
Photobiomodulation therapy using a diode laser

Primary outcome measure
Presence and severity of oral mucositis measured using the WHO scale and Oral Mucositis Assessment Scale OMAS at 7 and 14 days after the start of the first chemotherapy session

Secondary outcome measures
Secondary outcome measures are assessed at baseline, 7 and 14 days:
1. Oral Assessment measured using the Oral Assessment Guide (Eilers, Berger, and Petersen 1988)
2. Quality of life measured using the Oral Health Impact Profile (OHIP-14) and (PROMS) Patient-Reported Oral Mucositis Symptoms scale
3. xerostomia assessment using the LENT SOMA scale
4. Assay of saliva interleukin-6 (IL-6) by enzyme-linked immunosorbent assay (ELISA)
5. Measurement of nitrites in saliva using the spectroscopic method
6. Oral pain using a visual analogue scale (VAS)

Overall study start date
20/11/2022

Completion date
18/02/2024

Eligibility

Key inclusion criteria
Cancer patients undergoing chemotherapy for the first time with the same risk of mucositis:
1. Solid tumor patients
1.1. Chemotherapy (5-Fluorouracil) intravenously or orally
1.2. Neutrophil count ≥ 1500 cells/µL
1.3. Platelet count ≥ 100,000/µl
1.4. A healthy oral mucosa
1.5. Karnofsky performance status index >60

Participant type(s)
Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit

65 Years

Sex
Both

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
1. Radiotherapy in the head and neck area
2. Malignant or potentially malignant lesions of the oral cavity
3. Oral infections
4. Oral bleeding
5. Undergoing any other measures to prevent oral mucositis
6. Patients unable to commit to the study

Date of first enrolment
21/07/2023

Date of final enrolment
18/01/2024

Locations

Countries of recruitment
Syria

Study participating centre
Al-Biruni University Hospital
Damascus
Damascus
Syria
22743

Study participating centre
Al Assad Hospital
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Sponsor information

Organisation
Damascus University

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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
01/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Marwa Khalil, marwa.khalil@damascusuniversity.edu.sy

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/02/2025	07/02/2025	Yes	No