

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

<b>Submission date</b> 20/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

Dr Marwa Khalil

### Contact details

Lattakia

Lattakia

Syria

22743

+963 0991002787

marwa.khalil@damascusuniversity.edu.sy

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

### **Study type(s)**

Prevention, Quality of life

### **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](http://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

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Photobiomodulation therapy using a diode laser

### **Primary outcome(s)**

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

### **Key secondary outcome(s)**

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)

**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  $\geq 1500$  cells/ $\mu\text{L}$
  - 1.3. Platelet count  $\geq 100,000/\mu\text{L}$
  - 1.4. A healthy oral mucosa
  - 1.5. Karnofsky performance status index  $>60$

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

25 years

**Upper age limit**

65 years

**Sex**

All

**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**

Damascus

Damascus

Syria

22743

**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 analysed during the current study will be available upon request from Dr Marwa Khalil, [marwa.khalil@damascusuniversity.edu.sy](mailto:marwa.khalil@damascusuniversity.edu.sy)

### **IPD sharing plan summary**

Available on request

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>		05/02/2025	07/02/2025	Yes	No