

# A study comparing two types of laser therapy to reduce mouth pain and inflammation caused by cancer treatment in children with leukemia

<b>Submission date</b> 16/05/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/05/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/08/2025	<b>Condition category</b> 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

This study aims to compare the effectiveness of two types of laser therapy (high-level and low-level) in treating chemotherapy-induced oral mucositis in children with acute lymphocytic leukemia. The goal is to find out which treatment helps reduce pain and improve healing better.

### Who can participate?

Children between the ages of 6 and 13 who are receiving chemotherapy for acute lymphocytic leukemia and have developed oral mucositis can take part.

### What does the study involve?

Participants will receive one of three treatments: high-level laser therapy, low-level laser therapy, or a placebo treatment. Their progress will be monitored over several sessions to evaluate how well each treatment works.

### What are the possible benefits and risks of participating?

Participants may benefit from reduced pain and faster healing of oral mucositis. Risks are minimal but may include temporary discomfort from the laser treatment.

### Where is the study run from?

The Children's University Hospital, Damascus University, in the Hematology Department.

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

May 2024 to November 2025

### Who is funding the study?

Investigator initiated and funded.

### Who is the main contact?

Lana Kassem, Lann.aa1993@hotmail.com

# Contact information

## Type(s)

Public, Scientific, Principal investigator

## Contact name

Dr Lana Kassem

## Contact details

Floor 1 Badeer St

Damascus

Syria

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+963 935223292

lann.aa1993@hotmail.com

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

2931

# Study information

## Scientific Title

A randomized controlled trial comparing the efficacy of high-power and low-power laser therapy in the management of chemotherapy-induced oral mucositis in pediatric patients with acute lymphocytic leukemia

## Study objectives

The study hypothesizes that there is a difference in the efficacy of high-level laser therapy, low-level laser therapy, and placebo in the management of chemotherapy-induced oral mucositis in pediatric patients with acute lymphocytic leukemia. These differences are expected to be observed across three assessment time points: baseline, end of treatment, and one week post-treatment

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 12/08/2024, National Committee for Ethics of Scientific Knowledge and Technology, High Commission for Scientific Research, Syria (Damascus, Al-Sabe' Bahrat (Seven Lakes) – Former Prime Minister's Office Building, Syria, Damascus, 30151, Syria; +963-11-3341864; manager@hcsr.gov.sy), ref: 2931

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment, Efficacy

## Health condition(s) or problem(s) studied

Chemotherapy-induced oral mucositis in pediatric patients with acute lymphocytic leukemia

## Interventions

Current interventions as of 08/08/2025:

Participants will be randomly assigned to three groups. The first group will receive high-level laser therapy, the second group will receive low-level laser therapy, and the third group will receive a placebo (sham laser). The treatment will be applied once daily for a specified number of days during episodes of chemotherapy-induced mucositis. Laser parameters (power, wavelength, and duration) will be standardized for each group according to the intervention protocol. Outcomes will be assessed before treatment, at the end of treatment, and one week post-treatment.

Randomization Method: Random allocation was performed using the GraphPad online tool.

### High-Power Laser Protocol:

Type: Class IV Diode Laser (Doctor Smile) – Italy

Wavelengths: Combined 635–980 nm

Average Power: 2.75 W (5 W pulsed at 50%)

Area: 0.785 cm<sup>2</sup>

Application Time: 240 seconds per session

Total Energy per Session: 660 J

Energy density: 840 J/cm<sup>2</sup>

Application Mode: Defocused, non-contact, continuous wave, rotatory movement

Application Technique: Uniform sweeping rotatory motion with the tip approximately 1 cm from tissue, positioned orthogonally

Treatment Frequency: Once daily for four consecutive days

Target Area: Entire oral mucosa, including ulcerated, erythematous, and clinically unaffected sites

Wavelength Delivery: Combined wavelengths delivered simultaneously

### Low-Level Laser Therapy (LLLT) Protocol:

Laser Type: Class IV Diode Laser (Doctor Smile) – Italy

Wavelengths: Combined 635–980 nm

Average Power: 0.25 W

Dose per Session: 60 J

Area: 0.785 cm<sup>2</sup>

Fluence (Energy Density): 76.43 J/cm<sup>2</sup>

Application Time: 240 seconds per session

Mode: Defocused, non-contact, continuous wave mode, rotatory movement

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## Previous interventions:

Participants will be randomly assigned to three groups. The first group will receive high-level laser therapy, the second group will receive low-level laser therapy, and the third group will receive a placebo (sham laser). The treatment will be applied once daily for a specified number of days during episodes of chemotherapy-induced mucositis. Laser parameters (power, wavelength, and duration) will be standardized for each group according to the intervention protocol. Outcomes will be assessed before treatment, at the end of treatment, and one week post-treatment.

Randomization Method: Random allocation was performed using the GraphPad online tool.

### High-Power Laser Therapy (HPLT) Protocol

- Laser Type: Class IV Diode Laser (Doctor Smile)
- Wavelengths: Combined 660–970 nm
- Power Output: 3.2 W (6.4 W pulsed at 50%)
- Average Power: 3.2 W
- Pulse Frequency: 1–20,000 Hz
- Spot Size: 1 cm<sup>2</sup>
- Application Time: 231 seconds per session
- Total Energy per Session: 810 J
- Total Dose: 810 J per session
- Application Mode: Defocused, non-contact, continuous wave, rotatory movement
- Application Technique: Uniform sweeping rotatory motion with the tip approximately 1 cm from tissue, positioned orthogonally
- Treatment Frequency: Once daily for four consecutive days
- Target Area: Entire oral mucosa, including ulcerated, erythematous, and clinically unaffected sites
- Wavelength Delivery: Combined wavelengths delivered simultaneously

### Low-Level Laser Therapy (LLLT) Protocol

- Laser Type: Class IV Diode Laser (Doctor Smile)
- Wavelengths: 660 nm and 970 nm (combined)
- Power Output: 320 mW (0.32 W)
- Irradiance (Power Density): 320 mW/cm<sup>2</sup>
- Fluence (Energy Density): 36.8 J/cm<sup>2</sup>
- Spot Size: 1 cm<sup>2</sup>
- Energy per Area (per site): 16 J
- Application Time per Site: 50 seconds
- Total Number of Treated Areas: 9 intraoral sites
- Upper lip
- Lower lip
- Right cheek
- Left cheek
- Right lateral tongue
- Left lateral tongue
- Hard palate
- Soft palate
- Floor of the mouth
- Total Session Time: 450 seconds (7 minutes and 30 seconds)

- Application Mode: Defocused, non-contact, continuous wave mode, rotatory movement, tip held orthogonally to mucosal surface at a distance of approximately 1 cm
- Treatment Frequency: Once daily for four consecutive days
- Target Population: Pediatric patients undergoing chemotherapy for Acute Lymphoblastic Leukemia (ALL)

## **Intervention Type**

Device

## **Phase**

Not Applicable

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

Doctor Smile laser therapy device

## **Primary outcome(s)**

Oral mucositis severity measured using ChIMES, WHO Oral Mucositis Scale, NCI-CTC scale, and Modified Oral Assessment Guide (OAG) Scale at baseline, end of treatment, and one week post-treatment.

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

1. Weight measured using weighing scales at baseline and one week post-treatment
2. Absolute neutrophil count measured using CBC at baseline and one week post-treatment

## **Completion date**

30/11/2025

# **Eligibility**

## **Key inclusion criteria**

Current inclusion criteria as of 08/08/2025:

1. Pediatric patients aged between 3 and 13 years
2. Presence of clinically evident oral mucositis
3. Reported oral burning sensation
4. Currently receiving chemotherapy according to the standard protocol including methotrexate, cytarabine, and dexamethasone
5. Clear clinical signs of mucositis-related inflammation
6. Performance status score >2 on the ECOG (Eastern Cooperative Oncology Group) scale, as published by ECOG-ACRIN in 1982

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Previous inclusion criteria:

1. Pediatric patients aged between 6 and 13 years
2. Presence of clinically evident oral mucositis
3. Reported oral burning sensation
4. Currently receiving chemotherapy according to the standard protocol including methotrexate, cytarabine, and dexamethasone
5. Clear clinical signs of mucositis-related inflammation

6. Performance status score >2 on the ECOG (Eastern Cooperative Oncology Group) scale, as published by ECOG-ACRIN in 1982

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

13 years

**Sex**

All

**Key exclusion criteria**

1. Prior treatment with laser therapy for the management of oral mucositis
2. Presence of dysplastic lesions in the oral cavity
3. Patients receiving radiotherapy to the head and neck region

**Date of first enrolment**

15/02/2025

**Date of final enrolment**

30/11/2025

**Locations**

**Countries of recruitment**

Syria

**Study participating centre**

**Hematology and Oncology Unit - General Authority of the Children's University Hospital – Damascus**

Mezzeh Highway, adjacent to Al-Mowasat University Hospital

Damascus

Syria

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**Sponsor information**

## Organisation

Damascus University

## ROR

<https://ror.org/03m098d13>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Lana Kassem, Lann.aa1993@hotmail.com. The shared data will include individual participant data related to treatment outcomes and clinical assessments. Data will be anonymized to protect participant confidentiality. Data sharing will be granted for research purposes only, following ethical approval and with appropriate data use agreements. The data will be available starting from the publication date and for a period of five years.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	in Arabic		23/05/2025	No	Yes