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

Submission date
16/05/2025

Recruitment status
No longer recruiting

Registration date
23/05/2025

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Oral Health

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

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Additional identifiers

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^2
Application Time: 240 seconds per session
Total Energy per Session: 660 J
Energy density: 840 J/cm^2
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^2
Fluence (Energy Density): 76.43 J/cm^2
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^2
- 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^2
- Fluence (Energy Density): 36.8 J/cm^2
- Spot Size: 1 cm^2
- 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?
Participant information sheet	in Arabic		23/05/2025	No	Yes