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# Effect of combined photodynamic therapy and photobiomodulation therapy in the management of recurrent herpes labialis

**Submission date**
18/01/2025

**Recruitment status**
No longer recruiting

**Registration date**
20/01/2025

**Overall study status**
Completed

**Last Edited**
20/01/2025

**Condition category**
Infections and Infestations

[_] 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
Recurrent herpes labialis (RHL) is a common viral infection in the oral and facial areas. RHL is primarily caused by herpes simplex virus type 1 (HSV1). RHL is a global health problem, occurring in approximately 20 to 40% of young adults. RHL lesions are caused by physical and emotional stress, trauma, ultraviolet light, hormonal changes, and immunosuppression. This study aimed to compare Photodynamic therapy (PDT) combined with Photobiomodulation therapy (PBMT) and PBMT using a laser diode and acyclovir cream for treating RHL lesions by analyzing pain and healing parameters.

Who can participate?
Patients aged 19-50 years with RHL lesions.

What does the study involve?
Patients are randomly divided into three groups:
Group 1 (control): 5% Acyclovir was applied as a topical cream, and a non-activating laser was applied.
Group 2 (PBMT): PBMT was applied using a laser diode and a placebo cream.
Group 3 (PDT + PBMT): PDT using methylene blue with PBMT and a placebo cream.

What are the possible benefits and risks of participating?
Benefits: Participants will receive treatment for RHL.
Risks: There is a risk of an ineffective treatment.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2024 to January 2025

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

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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
Effect of combined photodynamic therapy and photobiomodulation therapy in the management of recurrent herpes labialis: a randomized controlled trial

### Study objectives
Combining PDT and PBMT in treating RHL lesions will enhance treatment results

### Ethics approval required

Ethics approval required

## Ethics approval(s)
Approved 13/05/2024, The Biomedical Research Ethics Committee (Mazzeh, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N2183

## Study design
Double-blinded randomized parallel-group active-controlled trial with three treatment arms

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
University/medical school/dental school

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Recurrent herpes labialis

## Interventions
Patients referred to the Department of Oral Medicine were evaluated for eligibility. From a total of 73 patients, 60 were randomly assigned into three groups (n = 20):
• Group 1 (control): 5% Acyclovir was applied as a topical cream (Veramed, Medico Labs., Damascus, Syria), and a non-activating laser was applied.
• Group 2 (PBMT): PBMT was applied using a laser diode and a placebo cream.
• Group 3 (PDT + PBMT): PDT using methylene blue with PBMT and a placebo cream.

In the control group, a 5% acyclovir cream was administered to the lesion five times a day over 5 days. A non-activating laser was also used on the lesion to ensure blinding. In the PBMT group, a laser diode emitting light at a wavelength of 650 nm and a power output of 100 mW was applied to each spot for 120 seconds. The laser diode treatment was carried out on the first day and again 48 hours after the initial application. In addition, the patient received a package including a placebo cream to be applied five times daily. In the PDT + PBMT group, the area was treated using a cotton ball dipped in sterile saline (SODIUM CHLORIDE 0.9% MIAMED, Miamed Pharmaceutical Industry, Damascus, Syria). A sterile needle tip punctured the vesicle to facilitate the drainage of its contents. The area was dried with sterile gauze within the lesion's borders, avoiding pressure or traction. The herpetic lesion was treated with a 0.01% methylene blue photosensitizer (Citrate Methylene Blue, 0.01% (w/v) 50mL, White labs., California, United States). After five minutes, the LLLT was applied. Any remaining traces of the photosensitizer were removed with a cotton ball soaked in sterile saline, again without pressure or traction. In addition, the LLLT, without the photosensitizer, was utilized 48 hours after the PDT, and the patient was provided with a placebo cream for application five times a day.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
1. Pain intensity
Pain intensity was measured using a visual analog scale (VAS), at the following time points:
• At the baseline (t0).
• After applying the laser in the first session (t1).
• Before applying the laser in the second session, after 48 hours (t2).
• After applying the laser in the second session (t3).
• After 7 days of follow-up (t4).
VAS scores were as follows:
• 0=No pain.
• 1–3=Mild pain.
• 4–6=Moderate pain.
• 7–9=Severe pain.
• 10=Worst pain possible.
2. Lesion healing
The point of healing was considered to be the spontaneous shedding of the crust from the lesion. Patients were followed up, and the day the crust fell off spontaneously was recorded.

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
05/05/2024

### Completion date
04/01/2025

## Eligibility

### Key inclusion criteria
1. Healthy participants.
2. Participants older than 18 years.
3. Participants had a history of RHL.
4. Participants had a current active vesicular infection.

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
19 Years

### Upper age limit
50 Years

### Sex
Both

### Target number of participants
60

### Total final enrolment
60

### Key exclusion criteria
1. Smokers.
2. Pregnant and breastfeeding women.
3. Diabetic patients.
4. Immunocompromised patients.
5. Participants were allergic to the agents used.
6. Patients had skin lesions that affected the course of healing or interfered with the current study.
7. Patients taking antiviral medications over the four weeks before treatment.
8. Patients taking anti-inflammatory drugs or antibiotics over the two weeks before treatment.

### Date of first enrolment
02/06/2024

### Date of final enrolment
06/12/2024

## Locations

### Countries of recruitment
Syria

### Study participating centre
**Damascus University**
Mazzeh highway
Damascus
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-

## Sponsor information

### Organisation
Damascus University

### Sponsor details

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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 peer-reviewed journal

**Intention to publish date**
01/03/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly (Mawiamaherkarkoutly@hotmail.com). The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

## IPD sharing plan summary

Available on request