STUDY PROTOCOL

Title:
Effectiveness of Photobiomodulation, Er:YAG Laser Therapy, and Clobetasol in the Treatment of the Erosive Form of Oral Lichen Planus: A Randomized Clinical Trial

Planned Study Period:

December 1, 2025 to December 1, 2027

The study will begin after approval from the Bioethics Committee.

I. STUDY OVERVIEW

Objective

The aim of this study is to evaluate and compare the therapeutic effectiveness of photobiomodulation (PBM), Er:YAG laser therapy, and topical clobetasol in the treatment of the erosive form of oral lichen planus (OLP). The study focuses on:

1. Healing rate of erosive lesions.
2. Reduction of pain intensity.
3. Improvement of oral function, including chewing, swallowing, and tolerance of removable prosthetic appliances.
4. Comparison of recurrence rates after treatment.

Rationale and Originality

Oral lichen planus is a chronic inflammatory disease of the oral mucosa, often associated with pain and impaired function, especially in the erosive variant. Topical corticosteroids, such as clobetasol, remain the standard of care, but long term use is limited by adverse effects and frequent relapses. Alternative therapies, including PBM and laser based treatments, have gained attention due to their potential benefits and improved safety profile. Evidence for the use of surgical or ablative lasers in erosive OLP remains limited and inconsistent. This study will directly compare three therapeutic modalities and provide clinically valuable information to support more effective and safer treatment strategies.

II. MATERIALS AND METHODS

Study Design

Randomized controlled clinical trial with three parallel arms.

Study Population

A total of 60 participants (male and female) aged 20 years or older will be recruited from the Clinic of Conservative Dentistry and Periodontal Diseases at the University Center of Dentistry, Medical University of Silesia in Zabrze, Poland.

Study Groups

Participants will be randomly assigned into three equal groups:

1. **Group 1:** Photobiomodulation (PBM)
2. **Group 2:** Er:YAG laser therapy
3. **Group 3:** Topical clobetasol (control)

Inclusion Criteria

- Age 20 to 70 years.
- Histopathological confirmation of erosive or ulcerative OLP.
- Absence of aerobic bacterial or fungal infection of the oral cavity.
- No OLP treatment within the past 3 months.
- Written informed consent.

Exclusion Criteria

- Systemic diseases or conditions including uncontrolled diabetes (random glucose ≥200 mg/dl), cardiovascular failure, pacemaker implantation, connective tissue diseases (such as lupus with positive ANA1 or ANA2).
- Current or past malignant disease.
- Graft versus host disease.
- Hematologic disorders including anemia, leukemia, lymphoma, bleeding disorders, hemophilia A, B, or C, and von Willebrand disease.
- G6PD deficiency, porphyria.
- Hepatitis A, B, or C.
- Vaccination within the past 6 months.
- Use of medications associated with lichenoid reactions, including beta blockers, diuretics, ACE inhibitors, methyldopa, sulfonylureas, lithium, gold salts, arsenic compounds, mercury, ibuprofen, tetracyclines, and sulfonamides.
- Pregnancy or breastfeeding, including up to 6 months post lactation.
- UV light hypersensitivity.
- Smoking more than 5 cigarettes per day.
- Lesions adjacent to amalgam fillings or metal prosthetic restorations.
- Presence of dysplastic changes of any grade.
- OLP treatment within 3 months prior to enrollment.
- Active fungal or bacterial infection.
- Lack of consent to participate.

Interventions

Group 1: Photobiomodulation (PBM)

- Diode laser 635 nm, power 100 mW, continuous mode, fluence 4 J/cm².
- Power density 0.2 W/cm².
- Exposure time 15 seconds per point.
- 8 mm flat glass fiber, spot size 0.5 cm², Gaussian energy distribution.
- Noncontact application at approximately 1 mm from the lesion.
- Sessions twice weekly until complete healing, maximum 8 sessions.

Group 2: Er:YAG Laser Therapy

- Pulse energy 80 mJ, frequency 10 Hz, power 0.8 W.
- Pulse duration 300 µs.
- Water cooling 5 and air cooling 5.
- 0.06 mm flat fiber, noncontact, 3 mm from lesion surface.
- Sessions once weekly until healing, maximum 4 sessions.

Group 3: Topical Clobetasol

- Clobetasol propionate 0.05 percent ointment.
- Applied to clean, dry mucosa twice daily for 30 days.

Pre Treatment Examinations

- Mycological and bacteriological swabs from both cheeks and posterior pharyngeal wall.
- Autofluorescence evaluation using a 405 nm diode laser to guide biopsy site selection.
- Histopathological analysis of a biopsy sample from the lesion.

III. CLINICAL ASSESSMENT

Assessment Schedule

- Baseline before treatment.
- One week after final session or cessation of steroid application.
- One month after treatment.
- Three months after treatment.

Clinical Parameters

- Lesion size in mm^2, including erosions, atrophic areas, and white lesions.
- Thonprasom scale grading from 0 to 5.
- Lesion size measured using transparent millimeter grid foil.

Scoring System

- R: reticular score
- A: atrophic score
- E: erosive or ulcerative score

Formula:
$REA = (R \times 1) + (A \times 1.5) + (E \times 2)$

Efficacy Index (EI)

EI = [(baseline REA score − post treatment REA score) ÷ baseline REA score] × 100 percent.

Interpretation:

- 100 percent: complete healing
- 75 to <100 percent: significant improvement

- 25 to <75 percent: moderate improvement
- 0 to 25 percent: slight improvement
- 0 percent: no improvement

Subjective Assessments

- Pain: Visual Analogue Scale (0 to 10).
- Swelling or discomfort: numeric scale (0 to 10).

Symptom Improvement (N)

N = [(baseline score − post treatment score) ÷ baseline score] × 100 percent.

Recurrence Evaluation

Follow up at 1 week, 1 month, and 3 months after treatment.

Mycological Testing

Performed before and after treatment to identify Candida colonization and secondary fungal infection.

IV. ETHICAL CONSIDERATIONS

The study will be conducted according to the Declaration of Helsinki. Ethics approval and written informed consent will be obtained before enrollment.

V. EXPECTED OUTCOMES

The study aims to identify the most effective treatment modality for erosive OLP, improving patient quality of life and reducing recurrence.

VI. POTENTIAL RISKS

Risks may include redness, swelling, pain, burning sensation, or changes in pigmentation. Rare risks include allergic reactions, photosensitivity, ulceration, or worsening of mucosal lesions.

VII. BENEFITS TO PARTICIPANTS

PBM and Er:YAG laser therapy may accelerate healing, reduce pain, support oral function, and offer a safer alternative to long term corticosteroid therapy. Laser procedures are noncontact and selective, minimizing injury to healthy tissue and promoting faster recovery.