STUDY SYNOPSIS

STUDY TITLE

Prospective monocentric study of a cohort of patients affected by Oral Lichen Planus: Cardiovascular and prothrombotic risk in patients affected by Oral Lichen Planus (OLP).

SPONSOR

FPG (Fondazione Policlinico Universitario A. Gemelli IRCCS)

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Co-Funder

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PRINCIPAL INVESTIGATOR

Prof. Carlo Lajolo

SINGLE ETHICS COMMITTEE OPINION

Yes

BACKGROUND AND RATIONALE

Oral Lichen Planus (OLP) is an autoimmune disease of unknown etiology, in which a lymphocytic response occurs against unknown antigens located in the basal and suprabasal layers of the oral mucosal epithelium. It is a chronic and incurable condition now classified as a potentially malignant disorder, with an increased risk of malignant transformation over time.

OLP affects approximately 2% of the global population, with increasing prevalence after age 40. Two main clinical forms have been described: one with hyperkeratotic, mostly asymptomatic lesions, and another with atrophic and erosive lesions often causing significant discomfort.

In recent years, cardiovascular risk has been associated with various dermatological conditions, and some studies have shown a possible association between lichen planus and dyslipidemia, as well as increased prevalence of atherosclerosis. Patients with OLP may present with higher levels of cardiovascular and metabolic risk markers compared to the general population, likely due to chronic inflammation.

Moreover, a strong association between immune system diseases and increased cardiovascular risk is already known. A recent Danish study involving 3,322 patients with autoimmune diseases found increased cardiovascular risks (e.g., cardiac arrest, cardiac atherosclerosis, venous thromboembolism, arrhythmia) in patients with cutaneous and oral vesiculobullous diseases.

STUDY OBJECTIVES

Primary Objective:

To evaluate the cardiovascular profile and the risk of thrombotic events in patients affected by Oral Lichen Planus.

Secondary Objectives:

To identify which markers and factors are most representative in assessing vascular risk in OLP patients.

ENDPOINTS

Primary Endpoint:

Prevalence of thrombotic risk.

Secondary Endpoints:

- Evaluation of thrombophilia screening parameters, antiphospholipid antibody levels, and platelet aggregability in a cohort of OLP patients.
- Association between collected parameters and incidence of thrombotic damage.

STUDY DESIGN

Single-center prospective observational study.

NUMBER OF PATIENTS

55 patients at FPG.

TARGET POPULATION

Patients diagnosed with Oral Lichen Planus.

INCLUSION CRITERIA

- Clinical and histological diagnosis of Oral Lichen Planus
- Age > 18 years
- Signed informed consent

EXCLUSION CRITERIA

- Patients < 18 years old
- Refusal to sign informed consent
- No diagnosis of OLP
- Known cardiac diseases
- History of major cardiovascular events (myocardial infarction, ischemic stroke, TIA)
- Established heart failure (NYHA class III–IV)
- Cardiomyopathies unrelated to the studied risk factors (e.g., genetic hypertrophic cardiomyopathy)
- Anticoagulant therapy
- Primary or secondary diseases associated with increased cardiovascular risk

STUDY DURATION AND ENROLLMENT PERIOD

Following Ethics Committee approval, the study will last 18 months: 12 months for consecutive enrollment of OLP patients and 6 months for data analysis.

STUDY PROCEDURES

Patients with a confirmed diagnosis of Oral Lichen Planus will undergo thrombophilia screening and cardiovascular risk assessment via hematological and laboratory tests.

STATISTICAL ANALYSIS AND SAMPLE SIZE

Sample size was calculated based on the simple random sampling formula. Assuming a 3.7% prevalence of prothrombotic risk in OLP patients and a desired absolute precision of 5%, a sample of 55 patients is required.

The primary endpoint (thrombotic risk prevalence) will be reported with a 95% confidence interval. The sample's clinical and demographic characteristics will be described using descriptive statistics. Qualitative variables will be reported as absolute and percentage frequencies; quantitative variables will be reported as means and standard deviations (SD) if normally distributed, or as medians and interquartile ranges (IQR) otherwise. Normality will be assessed using the Shapiro-Wilk test.

Associations between qualitative variables will be assessed using Fisher's exact test or the chi-square test, as appropriate. Quantitative variable differences will be tested using Student's t-test or the Mann-Whitney U test depending on normality assumptions.

A p-value < 0.05 will be considered statistically significant. Statistical analyses will be performed using SPSS version 25.0 (Chicago, IL, USA).

SAFETY / ADVERSE EVENT MANAGEMENT

Patients will be treated according to routine clinical practice. No study-specific procedures will be performed.

REFERENCE DOCUMENT FOR SAFETY

N/A

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