

# Use of light waves to take cross-section pictures of the mouth (optical coherence tomography) in patients with an inflammatory condition that affects mucous membranes inside the mouth (oral lichen planus)

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| <b>Submission date</b><br>14/04/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/04/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/08/2023       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

One of the most frequent diseases encountered in oral medicine is Oral Lichen Planus, an ongoing (chronic) inflammatory condition that affects mucous membranes inside the oral cavity, especially inner cheeks, tongue and gingiva. OLP may appear with white, lacy patches; red, painful lesions, or open sores. These lesions may cause burning, pain or other discomfort. Symptoms can usually be kept under control, but people with OLP need regular monitoring because they may be at risk, although very low, of developing oral cancer. To date, an oral biopsy (where a piece of tissue is removed in order to be analysed) is mandatory to have a proper diagnosis of OLP.

Recently, a novel diagnostic tool has been introduced in medicine, called Optical Coherence Tomography, a laser-like device which allows a real-time scan of diseases in other mucous membranes, such as the eye, and the skin.

Aim of the present study was to deploy OCT to scan the inner cheek of patients with red lesions from OLP, and to compare the results of this scan to both their oral biopsies and to OCT scans coming from the inner cheek of healthy patients, in order to assess if OCT could be used, in the future, as a valid diagnostic tool in oral medicine.

### Who can participate?

- 1) Adults aged 18 and older with a proper diagnosis of OLP, showing red lesions in their inner cheeks (Group of "cases")
- 2) Adults aged 18 and older requiring excision of lesions in the inner cheek caused by cheek biting (Group of "controls")

What does the study involve?

Both groups of "cases" and "controls" will be examined by an expert in oral medicine and then asked to open the mouth and stay still for 30 seconds, while the clinician scans their inner cheeks with OCT.

What are the possible benefits and risks of participating?

None. The scan with OCT is non-invasive and safe.

Where is the study run from?

Oral Medicine Section, CIR-Dental School, University of Turin, Italy

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

January 2020 to June 2020

Who is funding the study?

Università degli Studi di Torino (University of Turin), Italy

Who is the main contact?

Dr Marco Cabras, cabrasmarco300@gmail.com

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

DSCabras15

# Study information

## Scientific Title

In-vivo usefulness of optical coherence tomography in oral lichen planus: comparison between histopathological and ultrastructural findings

## Acronym

OCTOLp

## Study objectives

The aim of this study is to analyse and compare Optical Coherence Tomography (OCT) scans of healthy buccal mucosa and buccal mucosa affected by atrophic-erosive Oral Lichen Planus (OLP), using their histopathologic counterparts as main guideline, to understand if OCT could be a potential helpful tool for the clinician and the pathologist.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 12/2019, CIR-Dental School (Via Nizza 230, Turin, 10126, Italy; +39 116331522; segr\_cirdental@unito.it), ref: none provided

## Study design

Single-centre observational longitudinal case-control study

## Primary study design

Observational

## Study type(s)

Diagnostic

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

Oral Lichen Planus

## Interventions

Patients will be enrolled from those referring to the Oral Medicine Section of CIR Dental School, Turin, Italy.

Controls will be selected amid those requiring excision of traumatic benign lesions of the cheek.

Cases will be enrolled among those with a clinic-histological diagnosis of Oral Lichen Planus (OLP). Firstly, anamnestic data will be collected in both groups, to include only patients above 18 years old, able to understand verbal and written instructions, with no previous history of either oral premalignant disorders (i.e. oral leukoplakia, proliferative verrucous leukoplakia, erythroplakia) or oral squamous cell carcinoma/other malignancy of head and neck district. Secondly, oral examination will be carried out by an expert in oral medicine.

Controls will be examined to confirm the benign nature of the lesion within the buccal mucosa, in the form of a clinical diagnosis of either irritational fibroepithelial polyp, or fibrous hyperplasia.

Cases will be examined to intercept signs of atrophic-erosive OLP in the buccal mucosa, in the form of red, atrophic areas or erosions of the buccal mucosa, unexposed to any topical or systemic corticosteroid treatment for the previous 4 weeks.

Those patients responding to the aforesaid criteria will be briefly informed of the main characteristics of the OCT device and the purposes of the present trial. If willing to participate, they will be asked to fulfil and sign an informed consent form.

Finally, OCT scan will be acquired. It will consist on keeping the mouth open and still for 30 seconds, while the oral physician positions the oral probe of the OCT in contact with the atrophy/erosions caused by OLP, or with the healthy buccal mucosa surrounding the traumatic lesion.

After the scan is acquired, patient will undergo the regular follow-up and/or treatment required for their condition: cases with atrophic/erosive OLP will be administered with the appropriate therapy, whenever necessary, and followed up with monthly frequency until resolution of the symptoms.

On the other hand, controls with traumatic lesions will be evaluated for a subsequent surgical excision, to be performed in our own Department. Thus, a sample of healthy mucosa will be acquired and used for comparison as the histological counterpart of the OCT scan.

### **Intervention Type**

Device

### **Phase**

Not Applicable

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

Not applicable

### **Primary outcome(s)**

1. Average width, expressed in micrometers ( $\mu\text{m}$ ) of the stratified squamous epithelium (EP) and of the underlying lamina propria (LP) acquired using the OCT software and also from a biopsy, for comparison
2. Grade of reflectiveness of the stratified squamous epithelium (EP) and of the underlying lamina propria (LP) expressed through a grey-scale provided by the OCT software

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

None

### **Completion date**

01/06/2020

## **Eligibility**

### **Key inclusion criteria**

Cases:

1. Patients aged 18 and older
2. Attending the Oral Medicine Section of the Department of Surgical Sciences, Turin Hospital

3. Having clinic-histologically confirmed atrophic-erosive OLP
4. Showing signs of atrophy or erosion from OLP within the buccal mucosa
5. Being unexposed to topical or systemic steroid therapy in the previous 4 weeks.

**Controls:**

1. Patients aged 18 and older
2. Attending the Oral Medicine Section of the Department of Surgical Sciences, Turin Hospital
3. Referred for excision of traumatic benign lesions of the cheek (i.e. irritational fibroepithelial polyp, or fibrous hyperplasia)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

40

**Key exclusion criteria**

1. Histologically confirmed diagnosis of other oral premalignant disorder rather than OLP
2. Previous or concurrent histologic diagnosis of oral squamous cell carcinoma or other malignancy of head and neck
3. Incapacity to understand verbal and written instructions
4. Unable to stay still during the 30 seconds required for the OCT scan

**Date of first enrolment**

01/01/2020

**Date of final enrolment**

01/03/2020

**Locations**

**Countries of recruitment**

Italy

**Study participating centre**

University of Turin

Oral Medicine Section

CIR-Dental School  
Via Nizza 230  
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Italy  
10126

## Sponsor information

### Organisation

University of Turin

### ROR

<https://ror.org/048tbm396>

## Funder(s)

### Funder type

University/education

### Funder Name

Università degli Studi di Torino

### Alternative Name(s)

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Italy

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 24/08/2020   | 07/08/2023 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |