

# Risk of oral cancer in patients with oral lichen planus (a rash that can affect the inside of the mouth)

<b>Submission date</b> 27/07/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/01/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Oral lichen planus (OLP) is a rash that can affect different parts of your body, including the inside of your mouth. The most critical but possible complication of OLP is the development of mouth cancer, although this is a very controversial matter. At the end of the 80s, our group started to collect data to estimate the potential risk of malignant transformation in a Northern Italian cohort of OLP patients, and we published the first results in late 2004. In this new manuscript we finally reported our evaluation after 33 years of observation. To the best of our knowledge, this is the largest number of OLP patients ever reported with such follow-up period. Based on these results, the current concepts for malignant potential of Northern Italian OLP has been critically analysed.

### Who can participate?

Patients with OLP that attended a single hospital in Northern Italy between 1998 and 2020.

### What does the study involve?

Patient records will be analysed to find out if OLP led to cancer.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

CIR-Dental School, University of Turin (Italy)

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

January 1988 to December 2020

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof Arduino, paologiacomo.arduino@unito.it

## Contact information

### Type(s)

Scientific

### Contact name

Prof Paolo G Arduino

### ORCID ID

<https://orcid.org/0000-0002-8798-7834>

### Contact details

Via Nizza 230

Turin

Italy

10126

+39 (0)116331522

paologiacomo.arduino@unito.it

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Malignant transformation in subjects with oral lichen planus (OLP): a 33-year cohort study in Northern Italy.

### Acronym

CandOLP

### Study objectives

OLP is at risk for developing oral cancer in the follow-up period.

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

The study was approved by the ethical review board of the CIR-Dental School, University of Turin (CIR-PO-pga2020/09) which did not necessitate informed consent because of the nature of the study.

## **Study design**

Population-based cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other

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

Oral lichen planus

## **Interventions**

This study will involve the review of participants charts with OLP diagnosed between January 1988 and December 2020 at one hospital in Northern Italy.

## **Intervention Type**

Other

## **Primary outcome(s)**

Percentage of the histopathological diagnosis of oral cancer in OLP patients measured using patient records at a single time point

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

Measured using patient records at a single time point:

1. The tumour site
2. T classification and neck nodes association
3. Treatment modalities
4. Outcome and survival rate

## **Completion date**

31/12/2020

# **Eligibility**

## **Key inclusion criteria**

Conclusive diagnosis of OLP based on the following criteria:

1. Clinical confirmation with the presence of characteristic bilateral clinical signs [papular and/or reticular lesions (Wickham striae) alone or in association with atrophic or erosive lesions], not related to oral amalgam restorations;
2. Histological confirmation, through incisional biopsy, demonstrating the following microscopic characteristic:
  - 2.1. Presence of a well-defined band-like zone of cellular infiltration that is confined to the

superficial part of the connective tissue, consisting mainly of lymphocytes

2.2. Signs of "liquefaction degeneration" in the basal cell layer

2.3. Lack of epithelial dysplasia

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

3173

**Key exclusion criteria**

1. Unable or unwilling to provide informed consent
2. Significant psychiatric or cognitive impairment

**Date of first enrolment**

01/01/1988

**Date of final enrolment**

01/06/2020

**Locations**

**Countries of recruitment**

Italy

**Study participating centre**

CIR-Dental School  
University of Turin  
Via Nizza 230  
Turin  
Italy  
10126

**Sponsor information**

**Organisation**

University of Turin

ROR

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

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## 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>		16/11/2021	04/01/2022	Yes	No