

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

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

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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

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/1988

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

Age group

Adult

Sex

Both

Target number of participants

3,000

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
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Sponsor information

Organisation

University of Turin

Sponsor details

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Sponsor type

University/education

Website

<https://www.dentalschool.unito.it/it>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The results of the primary and secondary endpoints along with any other reportable data will be published in peer-review journal.

Intention to publish date

01/12/2021

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 16/11/2021 | 04/01/2022 | Yes | No |