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

Submission date
27/07/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
04/01/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

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.

Primary study design
Observational

Study design

Population-based cohort study

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