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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)

Submission date	Recruitment status	[_] Prospectively registered
14/04/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/04/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2023	Oral Health	

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
Dr Marco Cabras

ORCID ID
https://orcid.org/0000-0002-8240-5874

Contact details
Via Nizza 230
Turin
Italy
10126
+39 (0)116331522
cabrasmarco300@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 premaligant disorders (i.e. oral leukoplakia, proliferative verrucous leukoplakia, erytroplakia) 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 dignosis 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 measure
1. Average width, expressed in micrometers (μm) 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

Secondary outcome measures
None

Overall study start date

01/01/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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
Turin
Italy
10126

Sponsor information

Organisation
University of Turin

Sponsor details
Via Nizza 230
Turin
Italy
10126
+39 (0)116331522
paologiacomo.arduino@unito.it

Sponsor type
University/education

Website
http://www.unito.it/

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

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/06/2020

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		24/08/2020	07/08/2023	Yes	No