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# SurOL: Surgery for oral leukoplakia (a white patch in the mouth)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/11/2019 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/11/2019 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/12/2020 | Digestive System | |

## Plain English summary of protocol

Background and study aims
Leukoplakia is a white patch in the mouth. The WHO Collaborating Centres for Oral Precancerous conditions have clinically defined the term oral leukoplakia (OL) as “white mucosal lesions that have a risk of progressing to squamous carcinoma”. To date, the term OL should be used to recognize “predominantly white plaques of questionable risk having excluded (other) known diseases or disorders that carry no increased risk for cancer”. The vast majorities of OLs are localized lesions and follow a benign course. Small subsets of these lesions can become cancerous.
The aim of this study was to assess the effectiveness of surgery in the treatment of OL, in order to compare the "wait and see" approach in term of possible malignant transformation.

Who can participate?
Caucasian patients aged 18 years or above, with OL without signs of cancer

What does the study involve?
Participants will be randomly assigned to receive either surgical removal of the OL, or treatment as usual

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 2012 to December 2014

Who is funding the study?
Università degli Studi di Torino (University of Turin), Italy

Who is the main contact?
Prof. Paolo G. Arduino
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# Contact information

### Type(s)
Public

### Contact name
Prof Paolo G Arduino

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
DSarduino15

# Study information

### Scientific Title
A randomized no intervention-controlled trial of surgery in oral leukoplakia with no dysplasia

### Acronym
SurOL

### Study objectives
The aim of this study is to evaluate the surgical outcome of patients diagnosed with an oral leukoplakia without dysplasia, compared to patients with the same diagnosis who did not undergo surgery

### Ethics approval required

Old ethics approval format

### Ethics approval(s)
Approved 07/01/2009, CIR-Dental School (Via Nizza 230, Turin, 10126, Italy; segr_cirdental@unito.it), ref: AP-RB2009/1234

### Study design
Two arm randomized controlled trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Oral leukoplakia with no signs of dysplasia

### Interventions
Consecutive Caucasian patients, attending the Oral Medicine Section of the Department of Surgical Sciences, Turin Hospital, Italy, from January 2012 and December 2013, are selected for the present study. Participants are randomly divided into two groups. Allocation to treatment arms is performed using sequentially numbered randomization table. RANCODE (version 3.6) is used to generate the randomization sequence.

The first group of patients undergo surgical excision of the lesion with a traditional scalpel, (GROUP A_TS) whereas the second group of patients are followed up with no surgical session (GROUP B_NS).

The period of follow up is 5 years.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Malignant transformation of the biopsied lesion measured using visual inspection by a physician every six months

### Key secondary outcome(s))
Progression of the disease measured using visual inspection by a physician every six months

### Completion date
01/01/2020

## Eligibility

### Key inclusion criteria

1. Caucasian patients, attending the Oral Medicine Section of the Department of Surgical Sciences, Turin Hospital
2. Diagnosis of oral leukoplakia with no signs of dysplasia
3. Adults aged 18 and older

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
260

### Key exclusion criteria
1. Patients with a previous diagnosis of oral cancer.
2. Pregnant or lactating females; patients with incapacity to understand verbal and written instructions

### Date of first enrolment
01/01/2012

### Date of final enrolment
30/12/2014

## Locations

### Countries of recruitment
Italy

### Study participating centre
**CIR-Dental School; University of Turin**
Via Nizza 230
Turin
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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**
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/09/2020 | 02/12/2020 | Yes | No |