

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

Submission date 11/11/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/11/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/12/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
paologiacomo.arduino@unito.it

Contact information

Type(s)

Public

Contact name

Prof Paolo G Arduino

ORCID ID

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

Contact details

Via Nizza 230

Turin

Italy

10126

00390116331522

paologiacomo.arduino@unito.it

Additional identifiers

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

Italy

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