ISRCTN12617344 https://doi.org/10.1186/ISRCTN12617344

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
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

Primary study design
Interventional

Study design
Two arm randomized controlled trial

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