# Clobetasol propionate 0.05% versus placebo for the management of erosive oral lichen planus

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
04/11/2015		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
08/12/2015		[X] Results		
Last Edited	Condition category	Individual participant data		
18/04/2018	Skin and Connective Tissue Diseases			

## Plain English summary of protocol

Background and study aims:

Oral lichen planus (OLP) is a non-infectious, itchy rash that affects the mouth. To date, the most commonly employed and useful treatment for OLP is topical corticosteroids. The aim of this study is to assess the effectiveness of the corticosteroid clobetasol ointment, compared with a placebo (dummy) gel, for the treatment of OLP.

Who can participate? Patients over 18 years old with OLP.

#### What does the study involve?

The study is divided into two phases: phase I consisted of topical treatment for 2 months; phase II was a six-month follow-up period without therapy. Patients are randomly divided into two groups. One group receives clobetasol ointment mixed with a gel, while the second group receives only the gel. The participants are treated for 2 months and followed up 6 months later.

What are the possible benefits and risks of participating?

Topical steroids are an effective and safe treatment for OLP patients. Possible local minor side effects could be expected but they will disappear immediately after stopping treatment.

Where is the study run from? CIR – Dental School, Turin, Italy

When is the study starting and how long is it expected to run for? September 2015 to September 2016

Who is funding the study? University of Turin (Italy)

Who is the main contact?
Dr Paolo G Arduino
paologiacomo.arduino@unito.it

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Paolo Giacomo Arduino

#### **ORCID ID**

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

#### Contact details

Via Nizza 230 Turin Italy 10100 +39 (0)1633 1522 paologiacomo.arduino@unito.it

## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

Clobetasol propionate 0.05% versus placebo for the management of erosive oral lichen planus: a randomized controlled trial

#### Acronym

OLP\_clobvsplac

## Study objectives

Oral lichen planus (OLP) is a chronic inflammatory disease that can be painful, mainly in the atrophic and erosive forms. Numerous drugs have been used with dissimilar results, but most treatments are empirical and do not have adequate control groups or correct study designs. To date, the most commonly employed and useful agents for the treatment of LP are topical corticosteroids, but no data are available if compared with placebo treatment.

The aim of this study is to assess the efficacy of topical clobetasol 0.05%, compared with 4% hydroxyethyl cellulose bioadhesive gel, for the treatment of erosive oral lichen planus.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

CIR - Dental School, 04/04/016, Ref: CIR-Dental School - DRPGA -0026-2016

## Study design

Interventional single-centre trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Oral lichen planus

#### **Interventions**

The study is divided into two phases: phase I consisted of topical treatment for 2 months; phase II was a six-month follow-up period without therapy. Patients are randomly divided into two groups. Randomization is performed using computer-generated random number tables. The first group of patients received clobetasol 0.05% ointment mixed with a hydroxyethyl cellulose adhesive gel, whereas the second group of patients received only 4% hydroxyethyl cellulose bioadhesive gel. The medication are distributed in identical containers, packed by someone who was unaware of the study. The coded tubes were consecutively numbered according to the randomization list which was prepared and retained by a single clinician (R.B.). During treatment, neither the physicians nor the patients knew which of the two medications they were using.

## **Intervention Type**

Drug

#### Phase

Phase II/III

## Drug/device/biological/vaccine name(s)

Clobetasol

## Primary outcome(s)

Pain (visual analogue scale [VAS]) and clinical scores (Thongpranson scale) assessed at baseline, 4 weeks, 8 weeks, 20 weeks and 32 weeks

## Key secondary outcome(s))

- 1. Time taken to reduce signs and symptoms during the first two weeks of treatment
- 2. Length of remission from signs and symptoms

## Completion date

01/06/2017

## **Eligibility**

## Key inclusion criteria

1. Histological diagnosis of OLP on the basis of WHO criteria: hyperkeratosis of the superficial epithelial layers, vacuolar degeneration of the germinative layer of the epithelium and band-like

sub-epithelial lymphocytic inflammatory infiltrate

- 2. Presence of painful and atrophic-erosive oral lesions, at the same time with reticular ones
- 3. Ability to complete the present trial

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## Key exclusion criteria

- 1. Presence of histological signs of dysplasia
- 2. Use of lichenoid reaction inducing drugs and presence of amalgam fillings close to lesions
- 3. Therapy for OLP in the 2 months prior to the study
- 4. Pregnant or breastfeeding women
- 5. Proved or suspected hypersensitivity caused by the tested chemicals

#### Date of first enrolment

01/01/2016

#### Date of final enrolment

01/12/2016

## Locations

## Countries of recruitment

Italy

# Study participating centre CIR - Dental School, University of Turin

Via Nizza 230 Turin Italy 10100

# Sponsor information

## Organisation

University of Turin (Italy)

## ROR

https://ror.org/048tbm396

# Funder(s)

## Funder type

University/education

## Funder Name

University of Turin (Italy)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type	<b>Details</b> results	Date created Date added Peer reviewed? Patient-facing?			
Results article		01/07/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes