

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

Submission date 04/11/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

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?

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Contact information

Type(s)

Scientific

Contact name

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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No