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

Submission date
04/11/2015

Recruitment status
No longer recruiting

Registration date
08/12/2015

Overall study status
Completed

Last Edited
18/04/2018

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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

Overall study start date
01/01/2015

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

Age group
Adult

Sex
Both

Target number of participants
20

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
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
University/education

Funder Name
University of Turin (Italy)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/08/2016

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