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Use of Novox oil in the management of angular cheilitis

Submission date
12/02/2021

Recruitment status
No longer recruiting

Registration date
24/02/2021

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Angular cheilitis (AC) is a disease characterized by ulcers at the corner of the lips, forcing patients, especially children, to lick their lips. Clinically, it is characterized by redness, cracks in the skin, ulcers, and crusting of the lip corners and the surrounding skin, either in one corner of the mouth or both. There are several different causes of AC and recurrence of the disease. Infection of the skin by two microorganisms: Candida albicans and Streptococcus aureus, have been associated with the disease.

Antifungal treatments have been suggested as treatments but there is not much scientific evidence to show that this treatment is reliable. Access to oxygen is necessary for the healing process of tissue such as the skin and oxygen can also be used to kill certain microorganisms. This study aims to test how effective a hyper-oxidized oil-based gel known as is for patients affected by AC. This gel will deliver a higher concentration of oxygen to the areas affected by AC to promote healing and treat possible infection. The study will also collect microbiological swabs of the mouth and lips of patients with AC and healthy patients to compare the microorganisms present.

Who can participate?
Adults with a clinical diagnosis of angular cheilitis

What does the study involve?
Participants will be asked to use the medication Novox® Drop 2 times daily for 10 days. All patients will be carefully instructed on how to use the medication by applying the drop using a fingertip on the dried lesion after meals without eating, drinking, or speaking for at least half an hour afterward.

What are the possible benefits and risks of participating?
The direct benefit anticipated will be a reduction of reported pain.

The medication provided has been already used for other oral diseases, without showing any adverse effects. If the patients will manifest any reactions they will be recommended to stop the medication immediately and it is expected that in about one day adverse reactions will disappear.

Where is the study run from?
University of Turin (Italy)

When is the study starting and how long is it expected to run for?
From April 2018 to December 2021

Who is funding the study?
The University of Turin (Italy) supported the study. The MOSS spa (Italy) provided the medication used in the study.

Who is the main contact?
Prof Paolo Arduino
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Assessment of topical applications of Novox Drop™, a hyper-oxidized oil, in the treatment of angular cheilitis: an uncontrolled pilot study

Acronym
NDxACh

Study objectives
The use of Novox Drop™ twice daily for 10 days, could be useful in managing pain, and clinical appearance, in patients with angular cheilitis

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 01/02/2018, Azienda ospedaliera universitaria Città della Salute e della Scienza di Torino (Corso Bramante, 88/90, 10126 Torino, Italy; +39 0116334732; urp@molinette.piemonte.it), ref: CIR-PO-pga2018/01aa

Primary study design
Interventional

Study design
Prospective open-label non-randomized single-arm pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Angular cheilitis

Interventions
This is a prospective, open-label study, that involves giving a specific preparation (Novox® Drop is a class IIb medical device based on oxygen-enriched oil with Reactive Oxygen Species release) to a cohort of subjects with angular cheilitis. All patients were carefully instructed to apply the medication 2 times daily for 10 days using a finger rub application on the dried lesion after meals without eating, drinking, or speaking for at least 30 min afterward.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Novox Drop™

Primary outcome(s)
1. Spontaneous pain intensity measured using the Visual Analogue Scale (VAS), consisting of a 10 cm-horizontal line marked with 0 (=no pain) to 10 (=most severe pain experienced) at baseline and 10 days
2. Microbiological flora measured using clinical evaluation and oral swabs at baseline and 10 days

Key secondary outcome(s)
1. Clinical evaluation for the dimension of the lesion at baseline and 10 days
2. Unexpected effects of treatment recorded using a diary provided to patients between treatment start and 10 days

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Clinical diagnosis of angular cheilitis
3. No detectable oral mucosal lesions
4. Able to complete the present clinical trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Significant psychiatric or cognitive impairment
3. Pregnant or breast-feeding
4. History of allergy to ingredients present in Novox Drop™

Date of first enrolment
01/08/2018

Date of final enrolment
01/11/2020

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

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

Funder Name
MOSS spa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/12/2021	14/01/2022	Yes	No