

Use of Novox oil in the management of angular cheilitis

Submission date 12/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2022	Condition category Digestive System	<input type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Study design

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

Primary study design

Interventional

Secondary study design

Non randomised study

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 participant information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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

Sponsor details

Via nizza 230

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10126

+390116331522

paologiacomo.arduino@unito.it

Sponsor type

University/education

Website

<https://www.dentalschool.unito.it/it>

ROR

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

Publication and dissemination plan

The results of the primary and secondary endpoints along with any other reportable data will be published in peer-review journal.

Intention to publish date

01/06/2021

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