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Cannabis Sativa oil for the treatment of burning mouth syndrome

Submission date	Recruitment status	[_] Prospectively registered
09/04/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/05/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2020	Oral Health	

Plain English summary of protocol

Background and study aims

The International Headache Society has defined the Burning Mouth Syndrome (BMS) as “an intraoral burning or dysaesthetic (abnormal sensation) sensation, recurring daily for more than 2 hours per day over more than 3 months”.

The reported pain is described as moderate to severe, quite comparable to toothache in intensity, with a distinctive burning sensation, it is often accompanied by taste alterations and a dry mouth. By definition, clinical investigations and clinical sensory inspection are normal.

BMS management aims to reduce symptoms and pains, but no therapy has yet been shown to be effective. Currently, treatment is based on avoiding possible causes of mouth irritation and psychological support.

Cannabis (Cannabis sativa, or hemp) and its constituents (in particular the cannabinoids) have been the focus of extensive research. The plant's behavioural and psychotropic properties are attributed to its content of this class of compounds, the cannabinoids, which are produced mainly in the leaves and flower buds of the plant. There are also non-psychoactive cannabinoids with several medicinal functions, such as cannabidiol (CBD), cannabichromene (CBC), and cannabigerol (CBG), and many others.

In Italy, use of Cannabis sativa for therapeutic purposes (CTP) was first authorized in 2006. Suggestions for its use include chronic pain, nausea and vomitus associated to chemotherapy, appetite stimulation, low blood pressure in glaucoma, and lessening of uncontrolled body and facial movements.

This trial aims to test if the use of a full cannabis plant extract diluted in oil could be useful in reducing reported mouth pain.

Who can participate?

Adult patients with burning mouth syndrome

What does the study involve?
Patients suffering from atypical oral burning, with no detectable cause, will be enrolled. Participants will take cannabis oil for 30 days. Participants will be asked to complete questionnaires about their pain and wellbeing before they begin the study and at follow-up visits at 4, 12 and 36 weeks after the beginning of the study. Participants will be asked to record the treatment's unexpected effects in a diary.

What are the possible benefits and risks of participating?
Patients will be given a prescription and will receive the prescribed cannabis oil at the pharmacy to purchase independently. Cannabis oil will have to be used for 1 month, being careful not to drive or do jobs that require constant attention. Patients will be able to contact their doctor for any eventuality. Patients will be regularly followed up to 6 months after the end of therapy.

Where is the study run from?
CIR Dental School (Italy)

When is the study starting and how long is it expected to run for?
From February 2017 to November 2019

Who is funding the study?
This study is investigator-initiated and funded

Who is the main contact?
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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
Evaluating the feasibility, suitability and potential efficiency of Cannabis Sativa oil on pain and quality of life assessment for patients with burning mouth syndrome: a prospective open-label single-arm pilot study

Acronym
CANBMS

Study objectives
The use of a full cannabis plant extract diluted in oil could be useful in reducing reported oral reported pain not related to a specific clinical mucosal alteration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2017, 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-2017/01

Study design
A prospective open-label 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

Burning mouth syndrome

Interventions
This is a prospective, open-label study, that involves giving a galenic preparation of therapeutic Cannabis sativa to a cohort of subjects with an oral burning sensation. Caucasian patients, attending the Oral Medicine Section of the CIR Dental School, Turin, Italy, were selected for the present study.

Subjects with an oral burning sensation, classified as BMS according to the International Headache Society criteria, have been collected. Oil dose prescribed ranged from 10 to 40 drops, as the ideal dosing schedule is currently unknown (no dose-finding studies have yet examined the optimal daily amount of specific molecular concentrations of THC and CBD).

The schedule was prescribed as follows: 5 drops twice daily for 5 days, 10 drops twice daily for 5 days, 15 drops twice daily for 5 days, 20 drops twice daily for 15 days. The treatment was provided for 30 days. Follow-up visits were conducted at 4, 12 and 36 weeks after the beginning of the protocol study. The same expert oral physician performed the baseline conventional intraoral examination and follow up. Participants were provided with a diary to record the treatment's unexpected effects.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The full cannabis plant extract was prepared in specialised pharmacies starting from standardised cannabis plant material (cannabis flos) by means of Romano-Hazekamp or Sifap-Sifo extraction and diluted in oil (1 g of cannabis in 10 g of olive oil).

Primary outcome measure
Spontaneous pain intensity measured using the visual analogue scale (VAS), present pain intensity (PPI) scale, McGill Pain Questionnaire, and Oral Health Impact Profiles Profile questionnaires (OHIP-14, OHIP-19 and OHIP-49) at baseline, 4, 12 and 36 weeks

Secondary outcome measures
1. Levels of anxiety and depression measured using Hospital Anxiety and Depression Scale (HADS) and Geriatric Depression Scale (GDS) at baseline, 4, 12 and 36 weeks
2. Reported adverse events due to the THC treatment assessed from patient notes at the end of the study
3. Unexpected effects assessed from patient diary records collected at the end of the study

Overall study start date
01/12/2016

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Aged ≥ 18
2. Burning mouth syndrome diagnosis
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
15 patients

Total final enrolment
17

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Significant psychiatric or cognitive impairment
3. Other diagnoses that could explain the neuropathic pain
4. Diagnosis of Sjögren Syndrome on the basis of AECG criteria
5. Previous head and neck radiotherapy
6. Diagnosed lymphoma
7. Hepatitis C infection
8. Pregnant or breast-feeding women

Date of first enrolment
01/02/2017

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Italy

Study participating centre
CIR Dental School
Via Nizza 230
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Sponsor information

Organisation
University of Turin

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Sponsor type
University/education

Website
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ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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
01/06/2020

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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/02/2021	02/12/2020	Yes	No