

Does adding cannabidiol to a herbal mouth spray improve symptoms in people with burning mouth syndrome?

Submission date 04/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/10/2026	Condition category Digestive System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Burning mouth syndrome is a long-lasting condition in which people experience burning or painful sensations in the mouth even though no visible cause can be found. Treatment can be difficult, and cannabidiol has been suggested as a possible treatment for chronic and nerve-related pain. The aim of this pilot study was to find out whether adding cannabidiol to a herbal mouth spray could improve symptoms in people with primary burning mouth syndrome compared with the same herbal formulation without cannabidiol.

Who can participate?

Patients aged 18 years and over with primary burning mouth syndrome

What does the study involve?

Participants were randomly assigned to receive either a herbal mouth spray containing 5% cannabidiol or the same herbal formulation without cannabidiol. The two sprays were provided in indistinguishable packaging, and neither the participants nor the clinician assessing their symptoms knew which treatment they were receiving. Participants applied two sprays to the mouth four times a day for 45 days. Symptoms were assessed before starting treatment and again after 45 days. Assessments included pain intensity and characteristics, the impact of oral symptoms on quality of life, psychological symptoms, and sleep quality. Participants were also asked about possible side effects, difficulties using the spray, and treatment adherence.

What are the possible benefits and risks of participating?

Participants might experience an improvement in symptoms, although a direct clinical benefit could not be guaranteed. Possible risks included local sensitivity or discomfort related to use of the oral spray and potential treatment-related symptoms. Safety and tolerability were monitored during treatment and at the follow-up visit.

Where is the study run from?

University of Turin (Italy)

When is the study starting and how long is it expected to run for?

November 2021 to January 2024

Who is funding the study?

University of Turin (Italy)

The study received no specific financial funding from public, commercial, or not-for-profit funding agencies. The study formulations were developed, manufactured, and provided free of charge by Pi Greco Torino Sas, Turin, Italy.

Who is the main contact?

Prof. Paolo Giacomo Arduino, paologiacomo.arduino@unito.it

Contact information

Type(s)

Principal investigator, Public, Scientific

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Study information

Scientific Title

Cannabidiol as an adjunct to a phytotherapeutic mucosal spray for Burning Mouth Syndrome (CBD-BMS): a double-blind randomized controlled pilot trial

Acronym

CBD-BMS

Study objectives

The objective of this exploratory pilot study was to evaluate whether the addition of 5% cannabidiol to a phytotherapeutic oral mucosal spray provided additional clinical benefit compared with the identical phytotherapeutic formulation without cannabidiol in adults with primary burning mouth syndrome. The study assessed changes in pain intensity and pain-related features, oral health-related quality of life, psychological symptoms, and sleep quality, as well as the safety and tolerability of the two formulations over 45 days of treatment.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/04/2017, Board of the CIR-Dental School, University of Turin (Via Nizza 230, Turin, 10126, Italy; +39 (0)3356011953; segr_cirdental@unito.it), ref: CIR-PO-2017/01b

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Sequential

Purpose

Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Primary burning mouth syndrome (BMS)

Interventions

Participants were randomly allocated in a 1:1 ratio to one of two treatment groups. A computer-generated simple randomisation sequence with a 1:1 allocation ratio was prepared before enrolment by R.B., who had no involvement in participant recruitment, clinical assessment, or treatment administration. Participants were assigned sequentially according to the pre-generated randomisation list. The allocation code was retained exclusively by R.B. throughout the study and was not accessible to the investigators involved in participant recruitment or clinical and outcome assessments.

Intervention group:

Participants received a phytotherapeutic oral mucosal spray supplemented with 5% w/w crystalline cannabidiol (CBD). The background formulation contained a combination of phyto-micellar and water-soluble botanical extracts. Participants were instructed to apply two sprays to the oral mucosa four times daily, approximately at 10:00, 14:00, 18:00, and 22:00, for 45 days.

Control group:

Participants received the same phytotherapeutic oral mucosal spray without cannabidiol, following the identical administration schedule of two sprays four times daily for 45 days.

According to the manufacturer, the two formulations had the same qualitative background composition and were matched in appearance, packaging, manufacturing approach, and organoleptic characteristics; the intervention formulation additionally contained 5% w/w crystalline CBD. Participants and the clinician responsible for clinical and outcome assessments were blinded to treatment allocation.

Intervention Type

Other

Primary outcome(s)

1. Pain intensity measured using 10-cm Visual Analogue Scale (VAS) at baseline (T1) and after 45 days of treatment (T2)

Key secondary outcome(s)**Completion date**

06/01/2024

Eligibility**Key inclusion criteria**

1. Adults diagnosed with primary burning mouth syndrome according to the International Classification of Orofacial Pain (ICOP), 1st edition
2. Intraoral burning or painful dysaesthetic sensations occurring for at least 2 hours per day for more than 3 months, without clinically evident causative lesions
3. Body mass index $<30 \text{ kg/m}^2$
4. No previous systemic treatment with psychotropic medications
5. Absence of objective hyposalivation (unstimulated whole salivary flow $>0.1 \text{ ml/min}$)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

33

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Local or systemic disorders potentially responsible for oral burning, including clinically relevant laboratory abnormalities indicating a secondary cause
3. Psychiatric, progressive, or degenerative neurological disorders
4. Alcohol or substance abuse
5. Neoplastic or paraneoplastic disease of the upper aerodigestive tract
6. Immune-mediated oral disease
7. Inability to complete the study questionnaires

8. Treatment with medications potentially associated with oral burning, including angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, antidepressants, or other psychotropic drugs

Date of first enrolment

05/11/2021

Date of final enrolment

22/11/2023

Locations

Countries of recruitment

Italy

Sponsor information

Organisation

University of Turin

ROR

<https://ror.org/048tbm396>

Funder(s)

Funder type

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available