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Testing a new cannabidiol cream for vulvar pain relief: what the research shows

Submission date
05/07/2025

Recruitment status
No longer recruiting

Registration date
11/07/2025

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at a condition called vestibulodynia (VBD), which causes chronic pain around the opening of the vagina. Many women with VBD feel burning, stinging, or sharp pain, especially during sex or when using tampons. The study aims to test whether a gel containing cannabidiol (CBD) and myrcene—two natural substances with anti-inflammatory and pain-relieving properties—can help reduce this pain. Researchers believe that using these ingredients together might work better than using either one alone.

Who can participate?
Women aged 18 or older who have not yet gone through menopause can take part. They must have had VBD for at least six months, experience moderate to severe pain during most sexual activity, and have pain limited to the vestibule (the area around the vaginal opening). Participants must also have a stable sexual partner and be willing to try sexual activity during the study.

What does the study involve?
Participants will be randomly assigned to use either the CBD plus myrcene gel or a placebo gel (which looks the same but has no active ingredients). They will apply the gel once a day for 60 days. The study includes medical exams, pain assessments using rating scales, and questionnaires at the beginning and end of the study. Doctors will also check for any side effects.

What are the possible benefits and risks of participating?
Participants may experience relief from pain and discomfort. However, there is no guarantee of benefit. As with any treatment, there may be side effects, although the gel is expected to be safe. Participants will be monitored closely throughout the study.

Where is the study run from?
Ospedale dei Bambini Vittore Buzzi (Italy)

When is the study starting and how long is it expected to run for?
January 2024 to August 2025.

Who is funding the study?
Italian Vulvodynia Association

Who is the main contact?
Professor Filippo Murina, filippo.murina@unimi.it

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SDSM-2024-01.1

Study information

Scientific Title
Efficacy and safety of topical 5% cannabidiol plus myrcene for the treatment of vestibulodynia: a multi-centric randomized controlled trial. REief with topicaL cannAbinoids for VestibulodyniA

Acronym
RELEVA

Study objectives

The Research Hypothesis for the present study is to prospectively document the efficacy and safety of the topical association cannabidiol (CBD) plus myrcene in patients with vestibilodynia (VBD)21. The abundant distribution of cannabinoid receptors on skin nerve fibers and mast cells provides implications for an anti-inflammatory, anti-nociceptive action of cannabinoid receptor agonists and suggests their putatively broad therapeutic potential

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/01/2024, V. Buzzi Hospital (Via Castelvetro 24, Milan, 20124, Italy; +390263635420; prenotagine@asst-fbf-sacco.it), ref: protocol code 14/2024

Study design
Randomized double blind multicentric controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Tretment of patients with vestibulodynia, the most common manifestation of the vulvodynia

Interventions
One or more members of the staff who do not work directly with the subject will be responsible for assignment to active or placebo treatment based on random assignment. The patients will be trained to apply the gel to the vulvar vestibule (2 puff of the dispenser) once a day for 60 days, before the bedtime, with a follow-up after 60 days after the end of therapy.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Cannabidiol (CBD) plus myrcene (brand name Edonelle Plus)

Primary outcome measure
1. Pain intensity is measured using a 0–10 point visual analog scale (VAS) at baseline, 60 days, and 120 days
2. Dyspareunia is measured using a 0–10 point visual analog scale (VAS) at baseline, 60 days, and 120 days
3. Vestibular pain sensitivity is measured using the cotton swab test at baseline, 60 days, and 120 days
4. Percentage change in pain scores is measured using a 0–10 point visual analog scale (VAS) at baseline, 60 days, and 120 days
5. Absolute change in pain scores is measured using a 0–10 point visual analog scale (VAS) at baseline, 60 days, and 120 days

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
21/01/2024

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Women are at least 18 years of age and premenopausal, defined as having menstruated within the past 12 months
2. Women experience moderate to severe pain, defined as a minimum score of 4 out of 10 on a numeric rating scale, in at least one of three parameters (pain, dyspareunia, or swab test) during at least 90% of sexual intercourse attempts
3. Pain is localized to the vestibule during vaginal intercourse and during activities that exert pressure on the vestibule, such as tampon insertion, wearing tight jeans or pants, cycling, or horseback riding
4. Women have had a diagnosis of vestibulodynia (VBD) for at least 6 months, confirmed using a standardized gynecological examination protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
100

Total final enrolment
40

Key exclusion criteria
1. Women have active vulvovaginal infections at the time of their gynecological examination
2. Women have genital bleeding of unknown origin
3. Women are concurrently enrolled in other interventional clinical trials
4. Women are unwilling to provide informed consent to participate in the trial
5. Women have used topical drugs in the past 30 days

Date of first enrolment
15/03/2025

Date of final enrolment
30/03/2025

Locations

Countries of recruitment
Italy

Study participating centre
Vittore Buzzi Hospital
Via Castelvetro 24
Milan
Italy
20124

Study participating centre
ARNAS - Garibaldi Hospital
PiazzaSantaMariadiGesù5
Catania
Italy
95124

Sponsor information

Organisation
Ospedale dei Bambini Vittore Buzzi

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Sponsor type
Hospital/treatment centre

Website
https://ospedaledeibambini.it/noi-e-il-buzzi/

ROR
https://ror.org/044ycg712

Funder(s)

Funder type
Research organisation

Funder Name
Italian Vulvodynia Association

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to legal and ethical and local institutional rules.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1		07/07/2025	No	No