

Local delivery of cannabidiol in patients with vestibulodynia

Submission date 10/08/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/09/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/08/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Vulvodynia is a highly prevalent form of chronic genital pain in women and vestibulodynia is the prevalent subtype in which the pain is localized at the entry of vagina. The disease is related to nerve fibre inflammation. The aim of this study is to measure the effectiveness and safety of cannabidiol delivered using vestibular electroporation in patients with vestibulodynia. Cannabidiol has demonstrated significant pain-relieving, anti-inflammatory, and anti-neuropathic activities without the psychoactive effect. Electroporation is a painless technique to deliver drugs through microelectrical stimulation.

Who can participate?

Patients aged 18 years and over affected by vestibulodynia

What does the study involve?

Participants are randomly allocated to one of two groups:

Active group: patients will receive one treatment cycle of transmucosal delivery of cannabidiol (3 ml CBD 8% gel) using vestibular electroporation for six treatments total, once a week. This is followed by follow-up visits at 4 and 8 weeks.

Non-active group: patients in the placebo group will receive one treatment cycle of transmucosal delivery of placebo gel 3 ml using vestibular electroporation once a week for up to 6 weeks. This is followed by follow-up visits at 4 and 8 weeks.

What are the possible benefits and risks of participating?

The treatment may reduce or resolve the symptoms related to vestibulodynia (vulvar pain and/or pain at sexual intercourse). The researchers are not aware of adverse events related to the treatment.

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?

May 2022 to June 2023

Who is funding the study?
Associazione Italiana Vulvodinia (Italy)

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

Contact information

Type(s)

Principal Investigator

Contact name

Prof Filippo Murina

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

SDSM-2021-01.1

Study information

Scientific Title

Transmucosal delivery of cannabidiol using vestibular electroporation in patients with vestibulodynia: a randomized, blinded prospective trial

Acronym

DECANVBD

Study objectives

To prospectively document the efficacy and safety of transmucosal delivery of cannabidiol using vestibular electroporation in patients with vestibulodynia in order to reduce dyspareunia and vulvar burning/pain

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending, Buzzi Hospital Ethics Committee

Study design

Single-center interventional double-blinded randomized prospective trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Vulvodynia

Interventions

Randomization is determined by a computer-generated number list (MedCalc Version 20.110).

Active group: patients will receive one treatment cycle of transmucosal delivery of cannabidiol (3 ml CBD 8% gel) using vestibular electroporation for six treatments total, once a week. This is followed by follow-up visits at 4 and 8 weeks.

Non-active group: patients in the placebo group will receive one treatment cycle of transmucosal delivery of placebo gel 3 ml using vestibular electroporation once a week for up to 6 weeks. This is followed by follow-up visits at 4 and 8 weeks

Intervention Type

Procedure/Surgery

Primary outcome measure

Symptoms evaluated at baseline, 4 weeks and 8 weeks after treatment using:

1. 0-10 point visual scale (VAS) related to vulvar burning/pain and dyspareunia
2. Vestibular cotton swab test (small cotton-tipped applicator lightly rolled over the surfaces of the vestibule (mean of values at the 1, 3, 5, 6, 7, 9, and 11 o'clock locations by asking the subject to report pain intensity on a discrete visual analog scale of 1 (no pain) to 10 (worst possible pain).
3. Validated instruments: Female Sexual Function Index (FSFI), Vulvar Pain Functional Questionnaire (V-Q)

Secondary outcome measures

Evaluation of current perception threshold (CPT) testing (a technique which quantifies the sensitivity of vestibular nerve fibers) and vaginal EMG measurements, collected at states of rest and during several pelvic floor exercises through an EMG device with a vaginal sensor (Myotonus plus©-London-UK). The CPT values will be measured using the Neurometer CPT/C electrodiagnostic neurostimulator (Neurotron, Inc., Baltimore, MD), and vulvar vestibule CPT values will be determined using a G-trode Vaginal/ Rectal Electrode (Neurotron, Inc., Baltimore, MD). Measured at baseline, 4 weeks and 8 weeks follow-up visits.

Overall study start date

01/05/2022

Completion date

01/06/2023

Eligibility

Key inclusion criteria

1. Women at least 18 years of age and before the menopause
2. Experience moderate to severe pain (minimum of 5/10 on a numerical rating scale in at least 90 % of attempted sexual intercourse)
3. Pain limited to the vestibule during vaginal intercourse and during activities exerting pressure on the vestibule (tampon insertion, tight jeans or pants, cycling, horseback riding)
4. Presence of VBD for at least 6 months and diagnosed according to the standardized gynecological examination protocol by a staff gynecologist
5. Have a stable sexual partner (sexual activity should include some attempted vaginal penetrations to evaluate pain intensity)
6. Subject is willing to attempt sexual activity between visits
7. Read and signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

60 total, 30 patients active treatment, 30 patients control arm

Key exclusion criteria

1. Active vulvovaginal infections at the time of their gynecological examination
2. Genital bleeding of unknown origin
3. Patients concomitantly included in different interventional clinical trials
4. Unwillingness to provide informed consent

Date of first enrolment

01/06/2022

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

Italy

Study participating centre

Ospedale dei Bambini Buzzi di Milano

Lower Genital Tract Disease Unit

Via Castelvetro 22

Milano

Italy

20154

Sponsor information

Organisation

Ospedale dei Bambini Vittore Buzzi

Sponsor details

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20154

+39 (0)250042000

info@vulvodinia.org

Sponsor type

Hospital/treatment centre

Website

<https://ospedaledibambini.it/noi-e-il-buzzi/>

ROR

<https://ror.org/044ycg712>

Funder(s)

Funder type

Charity

Funder Name

Associazione Italiana Vulvodinia

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2023

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date