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Local delivery of cannabidiol in patients with vestibulodynia

Submission date
10/08/2022

Recruitment status
No longer recruiting

Registration date
11/09/2022

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
via Castelvetro 22
Milano
Italy
20154
+39 (0)2 63635420
filippo.murina@unimi.it

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 vestibolodynia 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
Via Castelvetro 22
Milan
Italy
20154
+39 (0)250042000
info@vulvodinia.org

Sponsor type
Hospital/treatment centre

Website
https://ospedaledeibambini.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