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A double blind, randomised, placebo controlled parallel group study of cannabis based medicine extract (CBME), in the treatment of peripheral neuropathic pain characterised by allodynia

Submission date
14/11/2005

Recruitment status
No longer recruiting

Registration date
18/11/2005

Overall study status
Completed

Last Edited
26/09/2019

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00711880

Protocol serial number
GWNP0101

Study information

Scientific Title
A double blind, randomised, placebo controlled parallel group study of cannabis based medicine extract (CBME), in the treatment of peripheral neuropathic pain characterised by allodynia

Acronym
GWNP0101

Study objectives
Tetrahydrocannabinol (THC):cannabidiol (CBD), 1:1 relieves peripheral neuropathic pain characterised by allodynia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Double-blind randomised placebo-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral neuropathic pain, characterised by allodynia

Interventions
THC:CBD, 1:1 and placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tetrahydrocannabinol (THC), cannabidiol (CBD)

Primary outcome(s)
Efficacy in relieving peripheral neuropathic pain after 5 weeks of treatment

Key secondary outcome(s))
1. Qualitative aspects of pain as reported the Neuropathic Pain Scale (NPS)
2. The physical and psychological effects of pain using measures of sleep disturbance, the Pain Disability Index (PDI) and General Health Questionnaire (GHQ-12)
3. Patients cognitive function using the Brief Repeatable Battery of Neuropsychological tests (BRB-N)

4. Patient perception of change in allodynia and pain on movement after 5 weeks of treatment
5. Tolerability of CBME using the adverse event profile, electrocardiogram (ECG), clinical laboratory tests and vital signs

Completion date
03/03/2004

Eligibility

Key inclusion criteria
1. Patient or legal representative is willing and able to give informed consent for participation in the study (if the patient is unable to read or to sign the document, consent procedures as detailed in the Declaration of Helsinki must be followed)
2. Male or Female, aged 18 years or above
3. Chronic peripheral neuropathic pain of at least 6 months duration
4. Presence of mechanical allodynia within the territory of the affected nerve(s)
5. Evidence of sensory change in the affected nerve by simple clinical tests
6. Pain with a severity score of 4 or more on at least 4 completed BS-11 scores in the baseline week
7. Stable dose of current analgesic medication for at least 2 weeks prior to study entry
8. Female patients of child bearing potential and male patients whose partner is of child bearing potential are willing to ensure that they or their partner use effective contraception during the study and for 3 months thereafter
9. Willing for his or her names to be notified to the Home Office for participation in this study
10. Willing to allow his or her General Practitioner and Consultant, if appropriate, to be notified of participation in the study
11. No cannabinoid use (cannabis, Marinolâ or Nabilone) at least 7 days before Visit 1 and willing to abstain from any use of cannabis during the study
12. Able (in the Investigators opinion), and willing to comply with all study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
145

Key exclusion criteria

1. History of schizophrenia, other psychotic illness, severe personality disorder or other significant psychiatric disorder other than depression associated with their underlying condition
2. Concomitant severe non-neuropathic pain or the presence of cancer related neuropathic pain or neuropathic pain resulting from diabetes mellitus
3. Known history of alcohol or substance abuse
4. Severe cardiovascular disorder, such as ischaemic heart disease, arrhythmias (other than well controlled atrial fibrillation), poorly controlled hypertension or severe heart failure
5. History of epilepsy
6. Female patient who is pregnant, lactating or planning pregnancy during the course of the study
7. Male patient who is currently receiving and unwilling to stop sildenafil (Viagra®) and unwilling to stop for the duration of the study
8. Regular levodopa therapy within 7 days of study entry
9. Significant renal or hepatic impairment
10. Known or suspected hypersensitivity to cannabinoids
11. Scheduled elective surgery or other procedures requiring general anaesthesia during the study
12. Terminal illness
13. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the patient at risk because of participation in the study, or may influence the result of the study, or the patients ability to participate in the study
14. Travel outside the UK planned during the study
15. Donation of blood during the study
16. Patients who have participated in another research study in the past 12 weeks
17. Patients previously randomised into this study

Date of first enrolment
13/05/2002

Date of final enrolment
03/03/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
GW Pharma Ltd
Salisbury
United Kingdom
SP4 0JQ

Sponsor information

Organisation
GW Pharma Ltd (UK)

ROR
https://ror.org/01gtctx88

Funder(s)

Funder type
Industry

Funder Name
GW Pharma Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2007	26/09/2019	Yes	No
Basic results			26/09/2019	No	No