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A one year open label assessment of the use of nabilone in the treatment of chronic neuropathic pain

Submission date 23/07/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2007	**Overall study status** Completed	
Last Edited 28/11/2019	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CL0022

Study information

Scientific Title

A one year open label assessment of the use of nabilone in the treatment of chronic neuropathic pain

Study objectives
The purpose of the study is to investigate the following:
1. Reported levels of pain in patients receiving nabilone for the treatment of chronic neuropathic pain for a period of one year
2. Patient tolerance of nabilone when used in the treatment of chronic neuropathic pain over a period of one year
3. Effects of nabilone on memory and psychometric function when used in the treatment of chronic neuropathic pain over a period of one year

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. South Tees Local Research Ethics Committee on the 26th March 2002 (ref: 00/51)
2. West Ethics Committee Glasgow on the 7th December 2001 (ref: 01/182)
3. Newcastle and North Tyneside Joint Ethics Committee on the 30th October 2001 (ref: 2000 /138)

Study design
One year open label non-randomised uncontrolled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mixed neuropathic pain

Interventions
Coming out of the cross-over trial mentioned in the inclusion criteria, patients with benefit on either of the study drugs was offered to participate in the open label trial. Nabilone capsules for oral intake were titrated in the first four weeks to 1 mg, then doubled to 2 mg if there were no side effects and then doubled again to 4 mg which was the maximum dose. The dose was then reduced to the lowest effective dose and the patient continued on this dose for one year if they did not decide to withdraw.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nabilone

Primary outcome(s)

Mean monthly pain scores compared to baseline: Visual Analogue Scale (VAS) scores were recorded daily in a diary together with hours slept and sleep interruption. Pain score were averaged over one month and compared to baseline every three months in the analysis.

Key secondary outcome(s))
1. Sleep was measured as hours slept and if the sleep was interrupted or not in the diary
2. Depression and anxiety were measured with the Hospital Anxiety and Depression Score (HAD) at baseline and then every three months
3. Depression
4. Quality of life was measured with the 36-item Short Form questionnaire (SF-36) at baseline and then every three months
5. Side effects were collected monthly with the eight-point questionnaire rating the severity of the side effects on a five point scale plus a field for open comments
6. Psychometric tests performed every three months

Completion date
01/01/2003

Eligibility

Key inclusion criteria
Patients with chronic neuropathic pain who have previously participated in the trial entitled: 'A randomised, crossover, double blind comparison of the analgesic effect and patient tolerability of nabilone and dihydrocodeine in chronic neuropathic pain' (see ISRCTN15330757) may enter this study. As such, patients will already have satisfied criteria for the diagnosis of chronic neuropathic pain.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients may not enter the study if they have a history of any of the following conditions:
1. Epilepsy
2. Liver disease
3. Psychosis
4. Bipolar disorder
5. Substance misuse
6. Renal failure
7. Adverse reactions to nabilone
8. Pregnant women, lactating women or women of childbearing potential not using effective methods of contraception

9. Patients involved in ongoing legal action against a third party in which financial compensation is being sought for personal injury alleged to be the cause of the presenting condition

Excluded medication:
Patients may not take the following medications during the study:
1. Antipsychotic drugs
2. Benzodiazepine drugs (excepting stable doses of night-time sedatives)
3. Monoamine oxidase inhibitors

Patients taking cannabinoid preparations of any kind may not be included in the study.

Date of first enrolment
01/10/2001

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
United Kingdom

Australia

Study participating centre
Flinders Medical Centre
Adelaide
Australia
5042

Sponsor information

Organisation
Cambridge Laboratories Ltd (UK)

ROR
https://ror.org/001zd1d95

Funder(s)

Funder type
Industry

Funder Name
Cambridge Laboratories Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration