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Pilot study of smoked cannabis for chronic neuropathic pain

Submission date	Recruitment status	[ ] Prospectively registered
11/10/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2010	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

JHM-50014

Study information

Scientific Title
Smoked cannabis for chronic neuropathic pain: a randomised controlled trial

Study objectives
The principle hypothesis of this study is that smoked cannabis containing 9.43% tetrahydrocannabinol (THC) is superior to that containing 0% THC in reducing pain intensity over a five day period, in patients with moderate to severe neuropathic pain.

Please note that this trial record was updated on the 18th January 2008 due to a protocol amendment which took place on the 8th February 2006. All changes to this trial record are entered under the date 18/01/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, McGill University Health Science Centre-Montreal General Hospital, Montreal, Quebec, Canada approved on 9th January 2002).

Updated as of 18/01/2008:
Full board approval for amendments were received on the 28th March 2006. However, please note that no patients were recruited on the amended protocol.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Cannabis containing 9.43% THC versus cannabis containing 0% THC.

Please note that the date of the last follow-up of the last recruited trial participant was 9th March 2006.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Average pain intensity measured daily during each cycle by 100 mm visual analogue scale (VAS)
2. No pain and worst pain possible will be used as anchors in the 11-item numerical rating scale. The daily pain intensity score will be averaged across all study days for each cycle to comprise the main outcome variable.

Secondary outcome measures
The main clinical outcomes will be the subjective 'high', mood, quality of life, and quality of sleep. Treatment discernment will be assessed by potency assessments at inpatient and follow up visits:
1. Trial feasibility: practical issues of recruitment and compliance will be recorded during the study
2. Pain quality: the McGill Pain Questionnaire (MPQ) measures affective and cognitive aspects of pain experience at patient visits. This will be administered on day five of each of the four five-day treatment cycles.
3. Sleep: a modification of the Leeds Sleep Evaluation Questionnaire (LSEQ) will be used. This will be administered by daily telephone interviews during each treatment cycle.
4. Mood: the short form Profile of Mood States (POMS) will be administered on day five of each of the four five-day treatment cycles
5. Quality of life: quality of life will be assessed using the EuroQOL 5D instrument, which will be administered on day five of each of the four five-day treatment cycles
6. Physiological assessments: physiological measurements (blood pressure, heart rate, electrocardiogram [ECG] changes, pulse oximetry, respiratory rate) will be conducted at 15 minute intervals during the first hour and hourly for two hours after smoking on day one of each treatment cycle
7. Quantitative sensory testing (QST): QST of cutaneous thermal sensitivity will be performed at baseline (during the screening visit) and on day five of each of the four five-day treatment cycles
8. 'High': will be measured subjectively at 15 minute intervals during the first hour and hourly for two hours after smoking on day one of each treatment cycle using an unmarked VAS scale (anchors: 0 is not at all, 10 is extremely)
9. Other subjective effects: the subjects will be asked to identify their current level of 'relaxed', 'stressed', 'happy' measured subjectively at 15 minute intervals during the first hour and hourly for two hours after smoking on day one of each treatment cycle using 100 mm VAS scales using the anchors 'not at all' and 'extremely'
10. Potency assessments: the patients ability to detect the strength of each cannabis preparation administered will be tested using subjective potency assessments. This will be administered on day one and day five of each treatment cycle.

Overall study start date

01/08/2003

Completion date
31/01/2006

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/01/2008:
1. Ambulatory, otherwise healthy, men and women with neuropathic pain of at least three months duration which is due to trauma or surgery, with clinical evidence of allodynia or hyperalgesia
2. Average weekly pain intensity score less than or equal to 4 on a 10 cm visual analogue scale (anchors: 0 is no pain, 10 is worst pain ever)
3. Stable analgesic regimen (no anticipated change in therapy over the next two months)
4. No cannabis use in the past month
5. Ability to comply with smoking procedure
6. 18 years and older
7. Ability to attend research centre twice weekly for four weeks over a two month period, and to be able to be contacted by telephone during the study period
8. Normal liver (aspartate aminotransferase [AST] less than 3 x normal) and renal function (serum creatinine less than 133 µmol/l)
9. Haematocrit greater than 35%
10. Negative serum beta human chorionic gonadotrophin [ßhCG] pregnancy test
11. Women of childbearing potential should use adequate contraception during study and for three months after study
12. Proficient in English or French
13. Willing and able to give written informed consent

Previous inclusion criteria:
1. Ambulatory, otherwise healthy, men and women with neuropathic pain of at least three months duration which is due to trauma or surgery, with clinical evidence of allodynia or hyperalgesia
2. Average weekly pain intensity score 5≤ on a 10 cm visual analogue scale (anchors: 0 is no pain, 10 is worst pain ever)
3. Stable analgesic regimen (no anticipated change in therapy over the next two months)
4. No cannabis use in the past month
5. Ability to comply with smoking procedure
6. 18 years and older
7. Ability to attend research centre twice weekly for four weeks over a two month period, and to be able to be contacted by telephone during the study period
8. Normal liver (aspartate aminotransferase [AST] <3 x normal) and renal function (serum creatinine <133 µmol/l)
9. Haematocrit >38%
10. Negative serum beta human chorionic gonadotrophin [ßhCG] pregnancy test
11. Women of childbearing potential should use adequate contraception during study and for three months after study
12. Proficient in English or French
13. Willing and able to give written informed consent

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32 (actual number of study participants recruited was 23)

Key exclusion criteria
Current exclusion criteria as of 18/01/2008:
1. Positive results of cannabinoid screening
2. Pain due to cancer or nociceptive causes (e.g. acute trauma, herpes zoster)
3. Unstable heart disease such as arrhythmias, cardiac failure, ischaemic heart disease, hypertension
4. Current substance abuse/dependence (including cannabis) as defined by the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM IV) criteria
5. Unstable or untreated lung disease (tuberculosis [TB], asthma, carcinoma, chronic obstructive pulmonary disease [COPD])
6. History of uncontrolled psychotic disorder in the past year (for example, schizophrenia or bipolar disorder)
7. Current suicidal ideation, as assessed by clinical psychologist
8. Pregnancy and/or breast-feeding
9. Participation in other clinical trial in the 30 days prior to enrolment
10. Ongoing medical insurance or compensation claims (may confound subjective pain intensity ratings if pain has possible secondary gain)

Previous exclusion criteria:
1. Positive results of cannabinoid screening
2. Pain due to cancer or nociceptive causes (e.g. acute trauma, herpes zoster)
3. Cardiac arrhythmias, cardiac failure, ischaemic heart disease
4. Current substance abuse/dependence (including cannabis) as defined by the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM IV) criteria
5. Pulmonary complications (tuberculosis [TB], asthma, carcinoma, chronic obstructive pulmonary disease [COPD])
6. History of psychotic disorder (for example, schizophrenia or bipolar disorder)
7. Current suicidal ideation, as assessed by clinical psychologist
8. Pregnancy and/or breast-feeding
9. Participation in other clinical trial in the 30 days prior to enrolment
10. Ongoing medical insurance or compensation claims (may confound subjective pain intensity ratings if pain has possible secondary gain)

Date of first enrolment
01/08/2003

Date of final enrolment

31/01/2006

Locations

Countries of recruitment
Canada

Study participating centre
McGill University Health Centre
Montreal
Canada
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Sponsor information

Organisation
Montreal General Hospital (Canada)

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lynn.derycapes@muhc.mcgill.ca

Sponsor type
Hospital/treatment centre

Website
http://www.muhc.ca

ROR
https://ror.org/04gbhgc79

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	05/10/2010		Yes	No