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Cannabis fOr Management of Pain: Assessment of Safety Study: COMPASS

Submission date	Recruitment status	[_] Prospectively registered
11/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2015	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOL-66262

Study information

Scientific Title
Cannabis fOr Management of Pain: Assessment of Safety Study: COMPASS

Acronym
COMPASS

Study objectives
The rationale for this long-term follow-up safety study is to facilitate a better understanding of how patients use cannabis, the number and nature of side effects in relation to exposure, and it would allow some exploration of the effects of cannabis on certain symptoms. The information gathered will assist in policy decisions and inform discussions of cannabis use between patients and physicians.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the McGill University Health Centre, Montreal General Hospital (Canada), 14/01/2004, ref: NREC#03-024

Study design
Multicentre two-arm open-label observational cohort safety study with one-year follow-up

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic non-malignant pain

Interventions
Experimental group: cannabis, daily up to 3g/day
Control group: standard therapy for pain

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Adverse events and adverse drug reactions*:
Time of measurement: this will be reported by the subjects during interviews at clinic visits, during telephone contacts, or at any time by calling the local study nurse up to one year
2. Neurocognitive tests (Wechsler scales, for experimental arm [cannabis users] and control arm [non-cannabis users]):
Time of measurement: baseline, six months and one year

*An "adverse event" means any adverse occurrence in the health of a clinical trial subject who is administered a drug, which may or may not be caused by the administration of the drug, and includes an adverse drug reaction. An "Adverse Drug Reaction (ADR)" means any noxious and unintended response to a drug that is caused by the administration of any dose of the drug.

Secondary outcome measures
1. Satisfaction with the study drug: a global rating of change in patient satisfaction with the provided drug will be generated for subjects and physicians using the Clinician's Global Impression of Change (CGIC) scale. This is an observational scale of global evaluation, which assesses the changes in degree of illness in relation to the original assessment, not just due to the study drug. The scale has only one item that measures global change of the illness (improvement or worsening) by the clinician and by the patients, separately, on a seven-point scale from zero to six. Change in satisfaction on this scale will also be examined with other measures of satisfaction such as dropout rates

Time of measurement:
Experimental arm (cannabis users): one month, two months, three months, six months, nine months, one year
Control arm (non-cannabis users): six months, one year

2. Effects on symptoms and quality of life:
a. Pain intensity: effects on pain intensity will be recorded using 0 to 10 numerical rating scales (0: no pain, 10: worst)
b. McGill Pain Questionnaire (MPQ): pain quality will be recorded using the MPQ. The MPQ is a self-administered questionnaire that evaluates the sensory, affective, and evaluative dimensions of pain and provides global scores and subscale scores for each of these dimensions
c. Edmonton Symptom Assessment Scale (ESAS): other symptoms will be monitored using the validated ESAS. The ESAS evaluates eight symptoms on visual analogue scores
d. Profile of Mood States (POMS): the POMS was developed to assess transient distinct mood states and has become the most popular and widely used tool to assess mood
e. Quality of life will be followed using the 36-item Short Form health survey (SF-36): SF-36 is a generic measure of perceived health status that incorporates behavioural functioning, subjective well-being and perceptions of health by assessing eight health concepts

Time of measurement:
Experimental arm (cannabis users): baseline, one month, two months, three months, six months, nine months, one year
Control arm (non-cannabis users): baseline, six months, one year

3. Feasibility of web-based adverse event reporting: will be assessed by ongoing documentation of the study monitoring process, specifically recording the issues that may arise during data collection using web-based forms (errors, misunderstandings, etc.,) and the manner and success of their resolution

Overall study start date
01/01/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Experimental arm and control arm (common criteria):
1. Adults 18 years or older, either sex
2. Chronic non-cancer pain for six months or longer
3. Moderate to severe pain (average weekly pain score on a 0 to 10 point scale of 5 or greater)
4. Ability to comply with protocol requirements
5. Proficient in reading and writing in English or French
6. Patient willing and able to give informed consent

Specific criteria (in addition to common criteria):
1. Experimental arm: conventional treatments have been considered medically inappropriate or inadequate
2. Control arm: patients must have received any prescription from the study physician in the past three months

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1400

Key exclusion criteria
Experimental arm and control arm (common criteria):
1. Pregnant or breast-feeding women
2. History of psychosis, including mental illness that could put subjects at risk during the study
3. Significant and unstable ischaemic heart disease or arrhythmia
4. Significant and unstable bronchopulmonary disease
5. Discordance between self-reported drug use and urine drug screening
6. History of drug dependency (including cannabis), or at risk of drug dependency identified by Drug Abuse Screening Test (DAST) and urine drug testing
7. Concurrent involvement in other clinical trial(s)

Specific criteria (in addition to common criteria):
1. Control arm: current cannabis use (use in the past month)

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Canada

Study participating centre
McGill University Health Centre
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Sponsor information

Organisation

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Sponsor type
Hospital/treatment centre

Website
http://www.muhc.ca/

ROR
https://ror.org/04cpxjv19

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	01/12/2015		Yes	No