

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

<b>Submission date</b> 11/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/10/2015	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

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**Type(s)**  
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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**

McGill University Health Centre (Canada)

**Sponsor details**

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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?
<a href="#">Results article</a>	results	01/12/2015		Yes	No