ISRCTN05531690 https://doi.org/10.1186/ISRCTN05531690

Post-operative analgesic effects of an oral cannabinoid

Submission date 24/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/02/2006	**Overall study status** Completed	
Last Edited 24/02/2009	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pierre Beaulieu

Contact details
CHUM - Hôtel-Dieu
Départment d'Anesthésiologie
3840, rue Saint-Urbain
Montreal
Canada
H2W 1T8
+1 514 890 8000 X 14570
pierre.beaulieu@umontreal.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-64678

Study information

Scientific Title
Post-operative analgesic effects of an oral cannabinoid: an efficacy and dose-response randomised controlled study

Study objectives
1. The major hypothesis is that nabilone decreases morphine consumption and nausea and vomiting following major surgery
2. The secondary objectives are to assess the anti-emetic effect of nabilone and to evaluate patients tolerability of the study medication

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité d'éthique de la Recherche de l'Hôtel-Dieu du CHUM Montréal approved on the 25th August 2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post-operative pain (in major orthopaedic, gynaecologic, abdominal and plastic procedures)

Interventions
Group A: 1 mg nabilone, one capsule of 1 mg + one capsule of placebo, 8 hourly
Group B: 2 mg nabilone, two capsules of 1 mg, 8 hourly
Group C: 50 mg ketoprofen, one capsule of 50 mg + one capsule of placebo, 8 hourly
Group D: placebo, two capsules of placebo, 8 hourly

Trial details received: 12 September 2005

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
A total (24 hours) morphine Patient Controlled Analgesia (PCA) consumption hours.

Secondary outcome measures
1. Pain intensity as measured by the Visual Analogue Scale (VAS)
2. Anti-emetic properties of nabilone
3. Assessment of mood and anxiety prior to surgery
4. Time to discharge criteria as indices of post-operative recovery
5. Quality of sleep
6. Incidence of side effects such as sedation, euphoria ('high'), psychotic episodes

Overall study start date
01/10/2003

Completion date
30/04/2005

Eligibility

Key inclusion criteria
1. Patients 18 - 75 years old, either sex, scheduled for major orthopaedic surgery
2. Patients using a morphine patient controlled analgesia (PCA) device post-operatively
3. Patients should be American society of Anaesthesiology (ASA) pre-operative status I, II or III
4. Patients 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
152

Key exclusion criteria
1. Patients using cannabis or other substance of abuse, alcoholism
2. Patients where morphine is not the drug of choice for PCA
3. Patients with planned concomitant medication during the study with any of the following: non-

steroidal anti-inflammatory drugs, acetaminophen, more than 300 mg acetyl salicylic acid per day, sedatives, anticonvulsants, antidepressants
4. Patients with ischaemic heart disease, cardiac arrhythmias failure
5. Patients with history of gastric or duodenal ulcer, renal insufficiency or asthma
6. Patients with chronic pain conditions and/or patients receiving chronic opioid therapy
7. Patients with history of psychiatric illness
8. Pregnant or lactating women

Date of first enrolment
01/10/2003

Date of final enrolment
30/04/2005

Locations

Countries of recruitment
Canada

Study participating centre
CHUM - Hôtel-Dieu
Montreal
Canada
H2W 1T8

Sponsor information

Organisation
Hôtel-Dieu de Montréal (Canada)

Sponsor details
3840 rue St-Urbain
Montréal
Canada
H2W 1T8

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0468gx405

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-64678)

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	01/08/2006		Yes	No