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Post-operative analgesic effects of an oral cannabinoid

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
A total (24 hours) morphine Patient Controlled Analgesia (PCA) consumption hours.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Hôtel-Dieu de Montréal (Canada)

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

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