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A clinical trial as proof of principle of the analgesic effectiveness of cannabinoids on postoperative pain

Submission date 23/10/2000	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2000	**Overall study status** Completed	
Last Edited 07/09/2009	**Condition category** Surgery	

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
G9901459

Study information

Scientific Title

Acronym
CANPOP

Study objectives
To determine if oral cannabinoids are analgesics and in the context of acute pain after surgery can provide pain relief. The primary outcome is the total pain relief score over 6 h based on hourly measurements from a verbal rating scale

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

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
Postoperative pain

Interventions
There are four groups with a single dose of one of the following administered at random:
1. Standardised cannabis plant extract
2. Tetrahydrocannabinol
3. Ibuprofen
4. Placebo

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The primary outcome is the total pain relief score over 6 h based on hourly measurements from a verbal rating scale

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/01/2001

Completion date
12/04/2004

Eligibility

Key inclusion criteria
Elective surgery for primary knee arthroplasties or gynaecological surgery (hysterectomies, myomectomies and tubal surgery). Written informed consent, cooperative, reliable, age 18-60 years, weight greater than or equal to 50 kg (July 2006: changed from 60 kg), able to take oral medication, at least moderate pain, approximately 24-48 h after surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
Preoperative pain medications. Analgesic drugs within 3 h of the study, surgical complications, haemorrhage (greater than 1000ml), ASA 3 or 4, any present or previous cardiovascular disease or medication, asthma, gastric ulcer, any present abnormal liver or renal function (as determined by laboratory tests), cannabis users within a month of the surgery, patients using sedatives, tranquillisers or anxiolytics, history of psychosis, pregnant (screening by pregnancy test) or

lactating women, participation in a clinical study in the previous month and patients previously entered into this study.

Date of first enrolment
01/01/2001

Date of final enrolment
12/04/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Magill Department of Anaesthesia
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/05/2006		Yes	No