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Ketamine plus morphine versus morphine alone for analgesic titration in the postoperative care unit

Submission date	Recruitment status	[ ] Prospectively registered
26/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2011	Signs and Symptoms	[ ] Record updated in last year

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

N/A

Study information

Scientific Title
Ketamine plus morphine versus morphine alone as a postoperative analgesic titration strategy in adult population: a randomised and double-blinded clinical trial

Acronym
Ketamorphine

Study objectives
Null hypothesis:
Adding ketamine to a morphine-based analgesic titration scheme does not decrease the morphine request, morphine-related side effects (nausea, vomiting, pruritus, respiratory depression), or time elapsed for adequate pain control (no pain/mild pain), during the staying of patients in the postoperative care unit of a third level hospital.

Alternate hypothesis:
Adding ketamine to a morphine-based analgesic titration scheme decrease the morphine request, morphine-related side effects (nausea, vomiting, pruritus, respiratory depression), or time elapsed for adequate pain control (no pain/mild pain), during the staying of patients in the postoperative care unit of a third level hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité de Bioética del Instituto de Investigaciones Médicas de la Facultad de Medicina de la Universidad de Antioquia approved on the 29th October 2009

Study design
Interventional randomised (computer generated) active controlled double blinded (participants + outcomes assessors) parallel multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-operative pain

Interventions
Interventional arm:
A 10 cc syringe filled with 10 mg of morphine (1 mg/ml) and 20 mg of ketamine (2 mg/ml) and saline. The patient receives intravenously 2 cc of the solution every 5 minutes until a clinical meaningful response is reached: mild pain or no pain at all. Treatment is administered during the post-operative care unit staying, only.

Control arm:
A 10 cc syringe filled with 10 mg of morphine (1 mg/ml) and saline. The patient receives intravenously 2 cc of the solution every 5 minutes until a clinical meaningful response is reached: mild pain or no pain at all. Treatment is administered during the post-operative care unit staying, only.

The duration of treatment as well as total duration of follow up is limited to the post-operative care unit staying, which is one hour.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ketamine, morphine

Primary outcome measure
1. Pain intensity measured by categorical and numerical (0 = no pain - 10 = unbearable pain) scale at 0, 15, 30, 45 and 60 minutes after start the intervention
2. Cumulative morphine requirement

Secondary outcome measures
1. Cumulated incidence of vomiting (presence/absence)
2. Nausea (presence/absence)
3. Anti-emetic requirement, (yes/no)
4. Pruritus (presence/absence)
5. Sedation (Ramsay Score)
6. Respiratory depression (O2 Sat less than 90 or RR less than 10 or naloxone requirement)
7. Hallucinations (yes/no)
8. Blurred vision (yes/no)

All variables will be measured at 15, 30, 45 and 60 minutes after the beginning of the intervention.

Overall study start date
25/03/2010

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Adult patients (aged greater than 17 years), either sex
2. Underwent surgery under general anaesthesia
3. State moderate or severe pain (pain intensity greater than 3/10)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
132 in total (66 in each arm)

Key exclusion criteria
1. Patients older than 80 years
2. Use of any regional analgesic technique (including neuraxial approach)
3. History of opioid or benzodiazepines or ketamine abuse, misuse or addiction
4. Chronic (greater than 3 months) opioid-based analgesic treatment
5. Pregnancy
6. History of a severe psychiatric disorder
7. Morbid obesity (body mass index [BMI] greater than 40 kg/m2)
8. Sleep apnoea
9. Vía aérea difícil (difficult airway)

Date of first enrolment
25/03/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Canada

Colombia

Study participating centre

76 Stuart Street
Kingston
Canada
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Sponsor information

Organisation
IPS Universitaria (Colombia) - Clinica Leon XIII

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Sponsor type
University/education

Funder(s)

Funder type
University/education

Funder Name
IPS Universitaria (Colombia) - Clinica Leon XIII

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