

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

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<b>Registration date</b> 07/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2011	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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/m<sup>2</sup>)
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

K7L 2V7

## **Sponsor information**

### **Organisation**

IPS Universitaria (Colombia) - Clinica Leon XIII

## **Funder(s)**

### **Funder type**

University/education

**Funder Name**

IPS Universitaria (Colombia) - Clinica Leon XIII

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration