# Effectiveness of peri-operative pregabalin as coadjuvant analgesic for cosmetic liposuction

Prospectively registered
Protocol
Statistical analysis plan
Results
Individual participant data
<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

### Scientific Title

Pregabalin as co-adjuvant analgesic for pain management after cosmetic liposuction: a randomised, double-blind and placebo-controlled clinical trial of effectiveness

## Study objectives

Null hypothesis:

Adding pregabalin to a conventional analgesic scheme does not decrease the pain intensity with movement, analgesic request, opioid-related side effects (nausea, vomiting, somnolence) or time elapsed for returning to regular activities in patients undergoing cosmetic liposuction.

### Alternate hypothesis:

Adding pregabalin to a conventional analgesic scheme decreases the pain intensity with movement, analgesic request, opioid-related side effects (nausea, vomiting, somnolence), or time elapsed for returning to regular activities in patients undergoing cosmetic liposuction.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)

Bioethics Committee of the IPS Universitaria (Universidad de Antioquia) (Comité de Bioética de la IPS Universitaria) (Universidad de Antioquia) approved on the 6th March 2006

## Study design

Interventional randomised placebo-controlled double-blind parallel multicentre 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

#### Interventions

Interventional arm:

Blinded capsules of pregabalin 75 mg. The patients started to take the medication the night before the surgery and continued the prescription twice daily (BID) up to the fourth day after surgery. They also had access to a prescription by the surgeon that included a weak opioid + acetaminophen and ibuprofen 200 mg as the circumstances arises (prn)

### Control arm:

Blinded capsules of placebo (physically identical to pregabalin capsules). The patients started to take the placebos the night before the surgery and continued the prescription BID up to the fourth day after surgery. They also had access to a prescription by the surgeon that included a weak opioid + acetaminophen and ibuprofen 200 mg prn.

### Intervention Type

Drug

### **Phase**

Phase IV

## Drug/device/biological/vaccine name(s)

Pregabalin

### Primary outcome measure

Numerical Rating Scale of Pain Intensity at rest and movement-induced at days 1, 2 3 and 4 after surgery

### Secondary outcome measures

- 1. Post-operative (days 1, 2 3 and 4) morphine-equivalent request
- 2. Incidence of nausea, vomiting and sedation at the same time-points

### Overall study start date

01/06/2006

## Completion date

01/09/2007

# **Eligibility**

## Key inclusion criteria

- 1. Women aged 18 70 years
- 2. American Society of Anesthesiologists physical status score I II
- 3. Scheduled for ambulatory cosmetic liposuction alone, liposuction and augmentation mammaplasty or liposuction and abdominoplasty under general anaesthesia

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Female

# Target number of participants

## Key exclusion criteria

- 1. Known allergy to any of the medications to be used (pregabalin, ibuprofen, tramadol or codeine)
- 2. Psychiatric illness
- 3. Chronic use (greater than 3 months) of steroids
- 4. Hypertension
- 5. Diabetes
- 6. Potential participants who were non-spanish speakers

### Date of first enrolment

01/06/2006

### Date of final enrolment

01/09/2007

# Locations

### Countries of recruitment

Canada

Colombia

# Study participating centre 76 Stuart Street

Kingston Canada K7L2V7

# Sponsor information

### Organisation

IPS University (IPS Universitaria) (Colombia) - Surgical Ambulatory Unit

### Sponsor details

Carrera 51A #62-42 Medellin Colombia

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+57(0) 4263 0171 ipsuniversitaria@ips.udea.edu.co

### Sponsor type

University/education

### Website

http://ips.udea.edu.co/

# Funder(s)

## Funder type

University/education

### Funder Name

IPS University (IPS Universitaria) (Colombia)- Surgical Ambulatory Unit, Department of Anaesthesia

# **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