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Effectiveness of peri-operative pregabalin as co-adjuvant analgesic for cosmetic liposuction

Submission date	Recruitment status	[ ] Prospectively registered
07/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/03/2011	Surgery	[ ] 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
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

110

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
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Sponsor type
University/education

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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