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The efficiency of tramadol, oxycodone and piritramide after an ambulatory gynaecological surgery

Submission date	Recruitment status	[ ] Prospectively registered
26/01/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/02/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/01/2016	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gynaecological surgery is the term given to any surgical procedures on the female reproductive system. Procedures can range from minor (ambulatory) such as dilatation and curettage (a procedure where tissue is removed from the womb to diagnose or treat certain conditions) to major, such as hysterectomy (removal of the womb). Pain after gynaecological surgery is not uncommon, and often the medications used to relieve pain causes unwanted side effects such as nausea, vomiting and dizziness. In AZ Nikolaas hospital (Belgium), the usual medication used for post-operative pain relief following minor gynaecological surgery is piritramide, which is known for causing many side-effects. It is a very powerful medication, which works by binding to receptors in the brain and blocking the feeling of pain. Tramadol and oxycodone are similar pain killers which work in the same way, but are thought to cause fewer side effects. The aim of this study is to compare the effectiveness and post-operative side effects of tramadol and oxycodone to piritramide in the relief of post-operative pain in patients undergoing ambulatory gynaecological surgery.

Who can participate?
Women over 18 years of age who are having ambulatory gynaecological surgery.

What does the study involve?
All participants have their surgery performed under general anaesthesia (sedation) using the drugs propofol and sufentanil, and receive 2g paracetamol with 75mg diclofenac, 4mg ondansetron and 1,25mg droperidol for pain relief. Participants are randomly allocated to one of three groups. Those in the first group are given oxycodone after their procedure for pain relief. Those in the second group are given tramadol after their procedure for pain relief. Those in the third group are given piritramide after their procedure for pain relief. While the participants are in the recovery room, they complete several questionnaires in order to measure their pain levels and satisfaction with the drug they have been given. Participants are also observed throughout the length of their hospital stay in order to monitor any side effects such as nausea, vomiting and dizziness.

What are the possible benefits and risks of participating?
Participants may benefit from lower levels of pain after their surgery. The risks of participating include the general risks of side effects, such as nausea, vomiting and dizziness from the study medications.

Where is the study run from?
AZ Nikolaas (Belgium)

When is the study starting and how long is it expected to run for?
March 2015 to May 2016

Who is funding the study?
AZ Nikolaas (Belgium)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The efficiency of tramadol, oxycodone and piritramide after an ambulatory gynaecological surgery: A randomised controlled trial

Study objectives
Tramadol and oxycodone lower the prevalence of postoperative nausea, vomiting and dizziness in patients undergoing ambulatory gynaecological surgery compared to piritramide.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical board of the hospital in Sint-Niklaas, ref: EC 15033

Study design
Prospective single-centre double-blind randomized controlled 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
Postoperative pain, nausea and vomiting after ambulatory gynaecological surgery

Interventions
Following provision of informed consent, participants are randomly allocated to one of three groups using envelope randomisation.

Group 1: Participants are given oxycodone for post-operative pain relief.

Group 2: Participants are given tramadol for post-operative pain relief.

Group 3: Participants are given piritramide for post-operative pain relief.

All procedures under general anaesthesia were performed a standardized anaesthetic regimen. Anaesthesia was induced with propofol and sufentanil. All patients were placed on mechanical ventilation and anaesthesia was maintained using sevoflurane in oxygen-air. During the surgery, the patients were administered 2 gram paracetamol with 75mg diclofenac, 4mg ondansetron and 1,25mg droperidol. All the patients were observed in the recovery room.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
1. Tramadol 2. Oxycodone 3. Piritramide

Primary outcome measure
Post-operative pain is measured using the Numeric Rating Scale (NRS) immediately after surgery (in the recovery room) and before hospital discharge.

Secondary outcome measures
1. Postoperative nausea (PON) and/or vomiting (POV) is recorded post-operatively throughout length of hospital stay
2. Postoperative dizziness is measured through observations in the recovery room immediately after surgery
3. Patient satisfaction is measured using a 4-point Likert Scale immediately after surgery

Overall study start date
12/03/2015

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Female
3. Ambulatory gynaecological surgery
4. Dutch speaking
5. General or spinal anesthesia
6. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
In this study, the aim is to obtain a minimum sample size of 300 patients with 100 patients in each arm.

Key exclusion criteria
1. Chronic pain
2. Mental disorder
3. Allergy Paracetamol, Tramadol, Oxycodon and/or Piritramide
4. Pregnancy
5. Breastfeeding
6. Emergency procedures

Date of first enrolment
16/11/2015

Date of final enrolment
15/04/2016

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Nikolaas
Moerlandstraat 1
Sint-Niklaas
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9100

Sponsor information

Organisation
University of Antwerp

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Faculty of Medicine and Healthcare
Division of Nursing Science and Midwifery
Universiteitsplein 1
Antwerp
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2610

Sponsor type
University/education

Organisation

Anenis

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Moerlandstraat 1
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Sponsor type
Hospital/treatment centre

Organisation
University of Antwerp

Sponsor details

Sponsor type
Not defined

Website
https://www.uantwerpen.be/en/

ROR
https://ror.org/008x57b05

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
AZ Nikolaas

Results and Publications

Publication and dissemination plan
Planned publication of results immediately after the statistical analysis.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date