

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

Submission date 26/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/01/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

1. Mrs Jelle Vermorgen (scientific)

Jelle.Vermorgen@aznikolaas.be

2. Dr Charlotte Stolte (scientific)

Charlotte.Stolte@aznikolaas.be

3. Mrs Nele Tulkens (scientific)

Nele.Tulkens@aznikolaas.be

4. Professor Bart Van Rompaey (scientific)

Bart.VanRompaey@uantwerpen.be

Contact information

Type(s)

Scientific

Contact name

Mrs Jelle Vermorgen

Contact details

Anenis

Moerlandstraat 1

Sint-niklaas

Belgium

9100

+32 3 760 85 48

jelle.vermorgen@aznikolaas.be

Type(s)

Scientific

Contact name

Dr Charlotte Stolte

Contact details

Anenis

Moerlandstraat 1

Sint-Niklaas

Belgium
9100
+32 3 760 85 48
Charlotte.Stolte@aznikolaas.be

Type(s)
Scientific

Contact name
Mrs Nele Tulkens

Contact details
Anenis
Moerlandstraat 1
Sint-Niklaas
Belgium
9100
+32 3 760 85 48
Nele.Tulkens@aznikolaas.be

Type(s)
Scientific

Contact name
Prof Bart Van Rompaey

Contact details
University of Antwerp
Universiteitsplein 1
Antwerp
Belgium
2610
+32 3 760 85 48
Bart.VanRompaey@uantwerpen.be

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

Belgium

9100

Sponsor information**Organisation**

University of Antwerp

Sponsor details

Faculty of Medicine and Healthcare

Division of Nursing Science and Midwifery

Universiteitsplein 1

Antwerp

Belgium

2610

Sponsor type

University/education

Organisation

Anenis

Sponsor details

Moerlandstraat 1
Sint-Niklaas
Belgium
9100

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