

Effect of gabapentin on morphine demand and pain after laparoscopic sterilization using Filshie® clips. A double blind randomised clinical trial

Submission date
07/06/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
05/07/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
25/09/2009

Condition category
Pregnancy and Childbirth

☐ Individual participant data

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

Study objectives

A considerable number of patients require opioids during recovery after laparoscopic sterilization. This implies nausea, dizziness and sedation and this increases the number of unplanned admissions. Gabapentin has shown excellent postoperative analgesic effects in a number of recent studies showing few side effects. This study was designed to test whether gabapentin given preoperatively can reduce the number of patients needing morphine in the recovery period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Regional Ethics Committee of Copenhagen County on 15/04/2002; reference number: KA 02028s

Study design

Randomised double-blind placebo-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Post operative pain after laparoscopic sterilization

Interventions

Females scheduled for laparoscopic sterilization using Filshie clips were randomised into two treatment groups (gaba group and control group).

All patients received lornoxicam 8 mg by oral administration (p.o.) for 30 min before the procedure. Patients in the gaba group received gabapentin 1,200 mg p.o. and patients in the control group received placebo capsules prior to the procedure.

All patients were anesthetized according to a protocol, using remifentanyl and propofol. Postoperative analgesia was obtained with patient-controlled infusion of morphine. Pain, nausea, dizziness and sedation were scored at two and four hours after end of anesthesia.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gabapentin, lornoxicam, remifentanyl, propofol, morphine

Primary outcome measure

The primary outcome measure was number of patients requesting morphine during the first four postoperative hours

Secondary outcome measures

1. Total morphine consumption from 0-4 hours postoperatively
2. Pain at rest and during mobilization from the supine to the sitting position
2. Side effects: nausea, sedation, dizziness, and vomiting

Overall study start date

01/09/2002

Completion date

01/11/2004

Eligibility**Key inclusion criteria**

Women presenting with laparoscopic sterilization that have also given their informed consent to participate, aged between 26 and 50 years old

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

80

Key exclusion criteria

1. Allergy toward gabapentin
2. Diabetes
3. Renal disease

4. Psychiatric disorder
5. Abuse of drugs
6. Analgesic treatment within 24 hours before the study
7. Treatment with steroids

Date of first enrolment

01/09/2002

Date of final enrolment

01/11/2004

Locations

Countries of recruitment

Denmark

Study participating centre

Department of Day Surgery

Herlev

Denmark

2730

Sponsor information

Organisation

Glostrup University Hospital (Denmark)

Sponsor details

c/o Jørgen B Dahl

Glostrup University Hospital

Department of Anesthesiology

Nordre Ringvej 29-67

Glostrup

Denmark

2600

Sponsor type

University/education

ROR

<https://ror.org/05p1frt18>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Copenhagen University Hospital at Herlev (Denmark)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/11/2006		Yes	No