ISRCTN39209275 https://doi.org/10.1186/ISRCTN39209275

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

Registration date
05/07/2006

Last Edited
25/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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 remifentanil 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, remifentanil, 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
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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