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Trial of steroids during hernia repair

Submission date 21/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 11/08/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 11/08/2010	**Condition category** Surgery	[ ] Individual participant data [ ] 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
EU-nr 2004-004280-30

Study information

Scientific Title
Randomised controlled trial of betamethasone versus placebo during open hernia repair

Acronym
Betopher

Study objectives
Betamethasone reduces postoperative pain and nausea after hernia repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uppsala Review Board approved on the 19th August 2004 (ref: 2004:M-029)

Study design
Double blind randomised placebo 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pain after groin hernia repair

Interventions
Patients are randomised to receive:
1. Betamethasone: 12 mg by intravenous injection at the induction of anaesthesia
2. Placebo: sodium chloride injection fluid at the induction of anaestheia
After the initial injection, anaesthesia is conducted according to the usual routines.

Intervention Type
Procedure/Surgery

Phase
Phase III

Primary outcome measure
Post-operative pain and nausea. Every half an hour postoperatively the level of pain is assessed using a visual analogue scale (VAS). Intake of food and drink, nausea or vomiting, VAS score when mobilised, medication, time for mobilisation and discharge from the unit are also recorded.

Secondary outcome measures
1. Time to discharge
2. Need of analgetics
3. Long-term postoperative pain

By discharge the patient receives a questionnaire to be recorded the first seven postoperative days. The patient is requested to record the daily use of medicines, the minimal and maximal VAS score for pain, ability to eat and drink, mobilisation, nausea, vomiting, or any other postoperative adverse events. The day after surgery the patient is contacted by phone and asked about VAS score for pain, ability to drink and eat, nausea, and mobilisation. One month after the operation the patient is contacted a second time by phone and asked about the presence of pain, any use of analgesics, problems related to the operation, and ability to perform normal working activity.

Overall study start date
01/01/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients aged 18 - 70 years undergoing open surgery for groin hernia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
400

Key exclusion criteria

Allergy to:
1. Paracetamol
2. Non-steroidal anti-inflammatory drugs (NSAID)
3. Sulfonamide antibiotics
4. Salicylate
5. Betamethasone

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Dept of Gastrointestinal Surgery
Stockholm
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Sponsor information

Organisation
Dalarna Research Institute (Dalarnas forskningsråd [DFR]) (Sweden)

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Sponsor type
Research council

Website
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Funder(s)

Funder type
Research council

Funder Name
Dalarna Research Institute (Dalarnas forskningsråd [DFR]) (Sweden)

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