

Trial of steroids during hernia repair

Submission date 21/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/08/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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 anaesthesia

After the initial injection, anaesthesia is conducted according to the usual routines.

Intervention Type

Procedure/Surgery

Phase

Phase III

Primary outcome(s)

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.

Key secondary outcome(s)

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.

Completion date

31/12/2008

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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
Sweden
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Sponsor information

Organisation

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

Funder(s)

Funder type

Research council

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration