Post-Operative Pain prevention after hepato-pancreato-biliary surgery: continuous sUbfascial infiltration orePidural analgesia? a randomized controlled non--inferiority multicenter trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23043

Source
Nationaal Trial Register

Brief title
POP-UP

Health condition

post-operative pain
wound infiltration
wound catheter
OBAS
epidural
hepato-pancreato-biliairy surgery
hpb surgery
wondkatheters
pancreas chirurgie
lever chirurgie

galweg chirurgie

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: AMC Amsterdam

Intervention

Outcome measures

Primary outcome

The primary endpoint is the Overall Benefit of Analgesic Score (OBAS) on day 1-5.

Secondary outcome

Total operative time (recorded as total time spent in the operating room, anaesthetic time, surgical time), length of hospital stay / readiness for discharge, failure of analgesic technique, pain every 12 hours until discharge at rest and movement
(VAS scores), cumulative opioid consumption, days CSWI/PCEA needed.
Side effects up to 30 days, including:
- Hypotension with the need for additional fluid boluses during and after surgery and noradrenaline dependency
Both at the end of surgery and at the end of PACU stay we will record:
1 duration of noradrenaline dependency and cumulative consumption
2 fluid boluses administered
3 fluid balance
- Prolonged post-anaesthesia care unit / Intensive care unit stay
- Duration of indwelling urinary catheter (yes/no) per day
- Pruritus, post-operative nausea and vomiting
- Complications related to anaesthetic technique, like CNS toxicity, epidural hematoma, epidural abscess
- Post-surgical pain after 30 days, 6 months and 12 months
- Existing pain? If yes, VAS?
- plasma levels in 20 patients after bolus injection.

Study description

Background summary

NA

Study objective

Post-operative pain prevention with CSWI+PCA provides similar analgesia (measured by OBAS) in comparison to PCEA with shorter total operation time and shorter length of hospital stay.

Study design

day 1-5, 6, 12 months

Intervention

Intervention: Continuous subfascial wound infiltration+PCA
Control: PCEA

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria
- Patients of 18 years and older
- Elective laparotomy for hepato-pancreato-biliary conditions:
„X Pylorus preserving pancreatoduodenectomy (PPPD), Whipple procedure
„X Distal pancreatectomy
„X Hepatojejunostomy
„X Partial liver resection

„X Other hepato-pancreato-biliary laparotomies (elective)
- Patients who have signed an informed consent form

Exclusion criteria

- ASA status >3
- Chronic opioid use (>12 months) and not for the indication of this operation
- Allergy to local anesthetics or morphine
- Renal / Liver failure
- Contraindications for epidural placement
- INR >1.5, PPT>1.5, Platelets <80

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2014
Enrollment:	102
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-01-2015

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4825
NTR-old	NTR4948
Other	POP-UP RCT : POP-UP trial

Study results