Postoperative pain reduction following umbilical hernia repair

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27010

Source
NTR

Health condition

umbilical hernia
postoperative pain
rectus sheath block

Sponsors and support

Primary sponsor: maxima medical centre
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

proportion of patients with a pain intensity of 3 or less, as assessed by the NRS

Secondary outcome

postoperative pain intensity as assessed by the NRS

postoperative use of analgesics

time to first dose of opiate analgesic

the incidence of PONV

the incidence of SAE related to USBRSB and LWI

Study description

Study design

10 minutes after arrival at the PACU

30 minutes postoperatively

3, 6, 12 and 24 hours postoperatively.

Intervention

ultrasound guided bilateral rectus sheath block

local wound infiltration.

Contacts

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Eligibility criteria

Inclusion criteria

Adult (>18 years old)

ASA-classification between I-III,

elective open primary umbilical hernia repair.

Exclusion criteria

- primary umbilical hernia repair via scopic

surgical technique.

- emergency umbilical hernia repair

- previous history of umbilical hernia repair.

- simultaneous repair of other hernia defects

- other surgical procedures performed during

the primary umbilical hernia repair.

- Patients with an ASA-classification >III.

- Patients with any contraindications for an ultrasound guided bilateral rectus sheath

block.

- allergy for LA drugs

- chronic treatment with analgesic drugs

- previous history with the medical

subspecialty of Pain Medicine.

- previous history of a laparotomy or stoma.

- no informed consent (IC)

- impaired mental capacity for self-determination.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2016
Enrollment:	66
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-06-2016

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	NL4056
NTR-old	NTR5940
Other	METC // CCMO : 15.122 // NL 54946.015.15

Study results