Elective Umbilical Hernia Repair: Outcomes of postoperative Pain in Adults after local Wound Infiltration or ultrasound-guided bilateral REctus Sheath block. (EUHROPA WIRES trial)

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To determine the reduction in pain after elective umbilical hernia repair (EUHR) in adult patients when using an ultrasound-guided bilateral rectus sheath block (USBRSB) versus local wound infiltration (LWI).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON47724

Source
ToetsingOnline

Brief title
EUHROPA WIRES trial

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Postoperative acute pain

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Afdeling Anesthesiologie van het Máxima Medisch Centrum te Veldhoven/Eindhoven.

Intervention

Keyword: Acute pain, Locoregional anaesthesia, Rectus sheath block, Umbilical hernia repair

Outcome measures

Primary outcome

The primary endpoint is the proportion of patients with a pain intensity of 3 or less, as assessed by the Numerical Rating Scale (NRS), at 10 minutes after arrival at the recovery, at 30 minutes postoperatively, and at 3, 6, 12 and 24 hours postoperatively.

Secondary outcome

The secondary outcomes are postoperative pain intensity as assessed by the NRS, postoperative use of opiate analgesics expressed as morphine equivalents, time to first dose of opiate analgesic, the incidence of postoperative nausea and vomiting (PONV), the incidence of serious adverse events (SAE) related to USBRSB and LWI (i.e. systemic local anaesthetic toxicity, peritoneal or intestinal puncture).

Study description

Background summary

Elective umbilical hernia repair (EUHR) is a commonly performed procedure in adults. A nationwide register-based study in Denmark [Burcharth, et al. 2015] reported that, over the 5-year period from January 1st 2006 until December 31st 2010, from a total of 5,639,885 people, 10,107 patients underwent umbilical

hernia repair. Males aged 60-70 years were found to have the highest 5-year prevalence 0.53% (95% CI 0.51-0.56%). [Burcharth, et al. 2015] At the Máxima Medical Center (MMC) Veldhoven-Eindhoven, a total of 83 and 111 EUHR were performed in respectively 2013 and 2014.
EUHR in adults is generally perceived as a minor procedure and mostly scheduled as day care surgery, with exceptions made depending on the patients* individual health status. A subset of day care patients, however, requires prolonged hospital length of stay (LOS), with pain being reported as the main reason (27% of cases), followed by major complications (19%) and seroma formation (9%). [Helgstrand, et al. 2011] Gerbershagen and colleagues conducted a large prospective cohort study including 70,765 adult patients, to investigate pain intensities during the first postoperative day for a broad range of surgical procedures. [Gerbershagen, et al. 2013] With respect to EUHR they report estimated mean pain intensities of NRS 4.73 and 4.20, for respectively a laparoscopic and open approach. [Gerbershagen, et al. 2013] As a reference, according to the local recovery and hospital discharge criteria at the MMC, patients need to have their postoperative pain levels controlled to a level of *acceptable pain*, which is generally comparable to an NRS of *3 by anesthesiologists. [NICE guideline: Ultrasound-guided regional nerve block. 2009.]
From an anesthesiologists* perspective, pain is therefore also the most important factor to improve, to contribute to better patient and healthcare outcomes with respect to EUHR.
At the MMC, current management of postoperative pain following EUHR as day care surgery involves intravenous non-opioid and short-acting opioid analgetics peroperatively, combined with LWI with long-acting local anaesthetic (LA) by the surgeon at the end of the procedure. In the postoperative period the intravenous non-opioid analgetics are continued via the oral route, while the intravenous short-acting opioid analgetics are switched to oral opioid analgetics, to allow same-day discharge. During the last decades, the combined use of ultrasound guidance and neurostimulation, by means of echogenic needles with neurostimulatory properties, has resulted in a subset of techniques that allow delivery of LA to strategic locations with high precision. [NICE guideline: Ultrasound-guided regional nerve block. 2009.] As a counterpart of LWI, these techniques are nowadays referred to as LRA. Important advantages of these techniques are (i) the ability to continuously visualize the needle point, minimalizing the risk of nerve damage or LA injection into the bloodstream; (ii) increased success rate with respect to analgetic effectivity; (iii) the ability to lower total administered doses of LA without decreasing analgesic effectivity, which decreases the risk of LA toxicity. [NICE guideline: Ultrasound-guided regional nerve block. 2009.] Disadvantages of LRA are the expensive ultrasound equipment needed, and the long training period to master the skills to administer LRA. [Baldi, et al. 2007.] So far, literature reports very low rates of morbidity and mortality associated with LRA, underlining the safety of these techniques. [NICE guideline: Ultrasound-guided regional nerve block. 2009.] With respect to EUHR and its associated postoperative pain, interest has risen in the effectiveness of the USBRSB to

improve postoperative analgesia for this surgical procedure. The USBRSB is one of the LRA. It specifically involves ultrasound-guided injection of LA bilaterally into the tendon sheath of the rectus abdominis muscle.
So far, only a limited number of studies have compared the analgesic effectiveness of the USBRSB with LWI in EUHR. All of these studies have been performed in paediatric patients and results are contradictory. [Dingeman, et al. 2013; Gurnaney, et al. 2011; Isaac, et al. 2006; Charlton, et al. 2010]
The current study protocol investigates USBRSB versus LWI with respect to postoperative pain following EUHR repair in adults, with the aim of decreasing both patient and healthcare burden in this patient population. We hypothesize that USBRSB with a long-acting LA, through its highly specific delivery into the rectus sheath compartment, is superior to LWI in terms of duration of low pain intensity (NRS *3).

Study objective

To determine the reduction in pain after elective umbilical hernia repair (EUHR) in adult patients when using an ultrasound-guided bilateral rectus sheath block (USBRSB) versus local wound infiltration (LWI).

Study design

Double-blinded, randomized controlled trial (RCT) in a single center non-university hospital in The Netherlands.

Intervention

In the intervention group, after induction of general anesthesia (GA) and before surgical incision, patients receive an ultrasound-guided bilateral rectus sheath block with 20 ml ropivacaine 0.75% by an experienced anesthesiologist (in-training). In the control group, patients receive local wound infiltration with 20 ml ropivacaine 0.75% by the surgeon (in-training) at the end of surgery.

Study burden and risks

Rectus sheath block under ultrasound guidance allows to continuously visualise the needle tip which, according to previous studies, translates into a safe performance of locoregional anesthesia (LRA). Literature reports a very low incidence of adverse events (AE) and serious adverse events SAE related to USBRSB. Patients receive the rectus sheath block or LWI under GA. During the postoperative period patients will be asked to fill out a short questionnaire (max 5 min) at four time points (3, 6, 12 and 24 hours postoperatively) with respect to their pain intensity, use of analgesics and possible PONV. The expected benefit is a decrease in incidence of moderate-to-severe pain (NRS >3)

after EUHR.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult (*18 years old) patients with an ASA-classification between I-III, who are planned for primary elective umbilical hernia repair.

Exclusion criteria

- Patients undergoing primary EUHR via scopic surgical technique.
- Patients undergoing emergency umbilical hernia repair or patients with any previous history

of umbilical hernia repair.
- Patients with simultaneous repair of other hernia defects or other surgical procedures performed during the primary EUHR.
- Patients with an ASA-classification >III.
- Patients with any contraindications for an USBRSB or LWI.
- Known allergies for LA drugs, or allergies for LA drugs that become apparent during the study course.
- Patients under chronic treatment with analgesic drugs or patients with any previous history with the medical subspecialty of Pain Medicine.
- Patients with any previous history of a laparotomy or stoma.
- Patients without informed consent (IC) and patients without the 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2016
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	18-03-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL54946.015.15