SUBLIME study: patient controlled sublingual sufentanil tablets versus intravenous morphine to enhance the quality of recovery after laparoscopic donor nephrectomy.

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To investigate if patient controlled sublingual sufentanil tablets as compared to patient controlled intravenous morphine lead to improved independent mobilization on postoperative day 1 after laparoscopic donor nephrectomy (LDN).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal and urinary tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46204

Source
ToetsingOnline

Brief title
SUBLIME study

Condition

- Renal and urinary tract therapeutic procedures

Synonym
Pain management after laparoscopic donor nephrectomy / keyhole surgery to remove a kidney

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Grunenthal,Grünenthal BV

Intervention

Keyword: Donor nephrectomy, Enhanced recovery after surgery, Laparoscopic surgery, Sublingual sufentanil

Outcome measures

Primary outcome

Independent mobilization (defined as patient reported use of the ward corridor bathroom without assistance) on postoperative day 1.

Secondary outcome

Quality of recovery on postoperative day 1 (QoR-40 questionnaire), quantitative mobilization measurements (HealthPatch® measured body posture and number of steps), heart rate variability, pain scores, postoperative nausea and vomiting, total dose of analgesics and anti-emetics, drug side effects, postoperative complications, length of hospital stay, re-admission within 30 days, ease of care nurse questionnaire and global daily cost of care.

Study description

Background summary

Use of the laparoscopic approach for surgical procedures is constantly increasing. This less invasive method of surgery has proven to be superior with regard to complication rate, morbidity, postoperative recovery and pain in many gastro-intestinal , , , hepatobiliary , , splenic , pancreatic , gynaecologic and urologic surgeries. However, pain management after laparoscopic surgery is complex. Even though laparoscopy is categorized as a medium-level procedure it can result in high levels of postoperative pain , complicated to treat because of its multifactorial origin. Pain after laparoscopy originates from port sites

or retrieval incisions, deep visceral pain from manipulated abdominal organs, inflammatory pain induced by tissue trauma or pressure related ischemia-reperfusion injury, or referred pain from distension-induced neuropraxia of the phrenic nerve . The multiple sources and types of pain after laparoscopy require a carefully planned multimodal pain management strategy. Nonetheless, an optimal pain treatment algorithm has not yet been defined.

Postoperative pain is an important influencing factor of recovery and length of hospital stay. Therefore, further research is needed to explore the best possible postoperative pain regimen in laparoscopy patients. Compared to open donor nephrectomy (ODN), laparoscopic donor nephrectomy (LDN) is also associated with less postoperative pain . As a relatively young and healthy population with little to no comorbidity, voluntary kidney donors constitute a valuable population for analysis. Pain and wound healing often comprise the most significant factors of their recovery. Optimising their pain treatment may enhance recovery and allow for a quicker return to normal daily activities.

The healthPatch® (figure 1a) from MediBioSense is a wearable biosensor that registers both vital signs and biometric measurements: a single lead ECG, heart rate variability, respiratory rate, skin temperature, body posture, and number of steps. The patch is applied to the skin on the left side of the chest and transfers information wirelessly. Validation studies show reliable measurement of heart rate (variability) , and ability to accurately monitor the acute stress response . Therefore, alongside patient reported outcomes, the patch allows for a subjective measure of pain and mobilization in postoperative patients at the ward.

Ideally, patients are in control of their own pain management. Studies show patient controlled analgesia (PCA) leads to lower pain scores and a higher patient satisfaction . Non-invasive patient controlled analgesia may improve early mobilisation, as no intravenous line is required . Moreover, non-invasive patient controlled methods can improve the ease of care for nurses at the ward . The Zalviso sublingual sufentanil tablet system (SSTS, figure 1b) provides effective pain management in laparoscopic abdominal and orthopaedic surgery . As the use of sublingual sufentanil tablets does not require intravenous access, early mobilization after surgery may be accelerated. Therefore, we hypothesize that the Zalviso sufentanil sublingual tablet system (SSTS), as compared to patient controlled intravenous analgesia (PCIA) with morphine, enhances postoperative mobilization and early quality of recovery after LDN.

Study objective

To investigate if patient controlled sublingual sufentanil tablets as compared to patient controlled intravenous morphine lead to improved independent mobilization on postoperative day 1 after laparoscopic donor nephrectomy (LDN).

Study design

A single centre prospective randomized non-blind comparative clinical trial.

Intervention

Patients will be randomly assigned in a 1:1 fashion to postoperative pain management with patient controlled sublingual sufentanil tablets or patient controlled intravenous morphine.

Study burden and risks

The burden associated with participation in the study is very small. The study compares two standard of care treatments, efficacy and safety of both treatments has already been established. If either treatment provides insufficient pain relief, additional analgesics will be administered. No invasive measurements will be performed. The HealthPatch® that is applied to the skin on the chest is small (115 x 40 x 7mm), lightweight (11 grams) and wireless, and will not interfere with clothing or normal daily activities. The HealthPatch® does not replace standard monitoring or care in any way. Assessment of pain, nausea, side effects and complications is part of routine clinical care. The quality of recovery (QoR-40) questionnaire will take approximately 10 minutes to complete.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Scheduled for living kidney donation
* Obtained informed consent
* Age *18 years

Exclusion criteria

* Inability to understand or follow instructions of use
* Contra-indications for patient controlled analgesia or opiates
* Chronic use of opiates
* Moderate to severe liver insufficiency (Child-Pugh score * 7)
* Severe renal insufficiency (eGFR <30ml/min/1,73 m2)
* Known or suspected allergy to morphine, sufentanil or one of the additives
* Signs of increased intracranial pressure, recent head injury or brain tumor.
* Biliary obstructive disorders or acute pancreatitis
* Bradyarrhythmia
* BMI > 35 kg/m2

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Morphine Hydrochloride
Generic name:	Morphine Hydrochloride
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zalviso
Generic name:	Sufentanil citrate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	14-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2018-002890-23-NL
CCMO	NL66713.091.18