Transitional Pain Service for patients at Risk of chronic postsurgical pain Undergoing Surgery

No registrations found.

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

Summary

ID

NL-OMON25531

Source
Nationaal Trial Register

Brief title
TRUSt study

Health condition

Chronic postoperative pain

Sponsors and support

Primary sponsor: Amsterdam University Medical Center, location Meibergdreef (AMC)
Source(s) of monetary or material Support: No external funding

Intervention

Outcome measures

Primary outcome

The primary outcome is the between group difference in Quality of Recovery (QoR)-15 questionnaire score at day three after surgery.

Secondary outcome

- Postsurgical chronic pain (CPSP) at three and six months after surgery, defined according to the IASP (as mentioned in chapter 1), and/or taking pain medication to treat CPSP as described above.
- Opioid consumption per day, calculated as morphine equivalent dose (MEDs) at day three after surgery, prescription at discharge, and at three and six months after discharge.
- Patient-reported outcome as measured by the WHODAS 2.0 (15), PROMIS-29 (16) and EQ-5D-5L (17) preoperatively and at three and six months after discharge.

Study description

Background summary

Patients with either surgery or patient-related risk factors (e.g. pre-existing chronic pain or preoperative opioid consumption) are at an increased risk of acute and chronic postsurgical pain (CPSP) and long-term opioid use. To improve recovery, prevent CPSP and decrease opioid use, we need to identify these patients before surgery and provide a multidisciplinary pain management strategy throughout hospital admission and follow up in the post discharge period. Randomized trials assessing the impact of a multidisciplinary transitional pain service (TPS) on quality of recovery, incidence of CPSP and opioid consumption have not been conducted yet and is the purpose of this study.

Study objective

The aim of our study is to investigate the effect of the implementation of a multidisciplinary TPS team for patients at risk of developing CPSP, on the quality of recovery, the incidence of CPSP and the opioid consumption. We hypothesize that the effect of implementation of a TPS team is superior to standard of care for outcomes as previously mentioned.

Study design

Baseline, 3 days postoperatively, 3 and 6 months postoperatively.

Intervention

Patients will be randomized to the TPS group or standard of care group. Patients allocated to the standard of care group will receive a pre-assessment at the outpatient preoperative evaluation (OPE) clinic. Postoperative pain will be managed by the Acute Pain Service (APS) for patients with an epidural, or peripheral nerve catheter or those with patient controlled analgesia (PCA). When the APS is not involved, postoperative pain will be managed by the surgeon and/or nurses on the ward.
In the TPS intervention group, the multidisciplinary TPS team, consisting of anesthesiologists

and nurses who are specialized in pain, will make an individualized perioperative pain management plan. If necessary, referrals to a psychologist, physiotherapist or social worker will be made. Education of the patient will take place.
After surgery, the APS, supervised by a member of the TPS team, will perform daily visits to monitor the effectiveness of pain treatment and to cease any medication that is deemed unnecessary. Following discharge from the hospital, the General Practitioner will be provided with information on the further pain treatment strategy for a better transition of care.
Patients will be scheduled for follow-up appointments at the TPS outpatient clinic, or receive follow-up telephone calls to re-evaluate the pain treatment plan, taper opioids and if CPSP is diagnosed, referred to a pain specialist after six months.

Contacts

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Eligibility criteria

Inclusion criteria

Patients aged 18 years or older
2. Willing and able to provide informed consent
3. Undergoing a surgical procedure with an increased risk of CPSP (amputation, spinal surgery, thoracotomy, breast surgery, herniotomy, hysterectomy and after arthroplasty) (9).

Or;

Any surgical procedure and one of the following:
- Diagnosed chronic pain, defined according to the ICD-11 as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Chronic pain is pain that persists or recurs for longer than 3 months (3)”
- Chronic opioid use, defined as > 20 mg daily morphine equivalent (MME) consumption for more than 3 months in the last 3 months

- Allergy to opioid agents
- Patients with pain device implants, such as intrathecal pain pump, spinal cord stimulation or peripheral nerve stimulator
- The usage of pain medication as methadone, buprenorphine, anticonvulsants, antidepressants or medicinal cannabis for chronic pain for more than 3 months in the last three months
- Psychosocial comorbidities like anxiety, depression, pain catastrophizing if documented in the electronic medical record

Exclusion criteria

- Patients who undergo emergency surgery are excluded to ensure sufficient time for the informed consent process.
- Patients undergoing implementation of pain device implants, such as intrathecal pain pump, spinal cord stimulators or peripheral nerve stimulator.
- Patients who undergo surgery that most likely leads to prolonged sedation and for that reason cannot fill in the QoR-15 questionnaire at day three postoperative.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	176
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be made available on request after an embargo period. After the last manuscript is published, data will be made available, with restricted access. Agreement regarding the following conditions will be needed before data sharing:
· Permission from the participants to send data outside of the EU (if applicable)
· Approval from the Steering Committee and Project Manager for the proposal
· Financial compensation for costs, for example, to obtain data after being archived
· A period of permission to use the dataset will be set
· The format in which the dataset will be made available will need to be discussed
· Approval to couple the dataset to another dataset (privacy) will have to be discussed
· There are provisions with regard to data safety and privacy laws
· Collaboration over use of the dataset, including agreements over publications and authorships
· Agreements regarding methodology
A proposal, in the correct format will be assessed by the Steering Committee. If the research question is deemed relevant, a well-defined analysis plan is available, agreements are made regarding publication, and all other requirements are met, then the Steering Committee will give permission to share the data.

Ethics review

Positive opinion

Date:	11-12-2020
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	NL9115

Register	ID
Other	METC AMC : METC2020_211

Study results