

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

No registrations found.

| | |
|------------------------------|------------------|
| Ethical review | Positive opinion |
| Status | Pending |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON26410

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

Public

Amsterdam UMC, locatie Meibergdreef
Manouk Admiraal

0682346824

Scientific

Amsterdam UMC, locatie Meibergdreef
Manouk Admiraal

0682346824

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

- Not willing or able to provide written informed consent
- Emergency surgery

Study design

Design

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

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2020 |
| Enrollment: | 180 |
| Type: | Anticipated |

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion

Date: 28-08-2020

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 | NL9015 |
| Other | METC AMC : METC2020_211 |

Study results

Summary results

N/A