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

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We aim to investigate the effectiveness of implementation of a TPS compared to standard of care (SOC) for patients at risk of developing CPSP, as measured by quality of recovery, incidence of CPSP and opioid consumption.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49357

Source
ToetsingOnline

Brief title
The TRUSt study

Condition

- Other condition

Synonym
Chronic postsurgical pain

Health condition

Pijn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Analgesics, Chronic postoperative pain, Operative, Opioid, Surgical Procedures, Transitional Pain Service (TPS)

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

Secondary outcomes are the incidence of CPSP, opioid consumption and

patient-reported outcome measures.

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

We aim to investigate the effectiveness of implementation of a TPS compared to standard of care (SOC) for patients at risk of developing CPSP, as measured by

quality of recovery, incidence of CPSP and opioid consumption.

Study design

Pragmatic, open label, randomized controlled trial.

Intervention

Patients will be randomized to the TPS group or SOC group. Patients allocated to the SOC group will receive a pre-assessment at the outpatient preoperative evaluation (OPE) clinic. Postoperative pain will be managed per protocol by the Acute Pain Service (APS) for patients with epidural analgesia, peripheral nerve catheter or using 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 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. 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.

Study burden and risks

There are no safety risks associated with this study. Patients randomized to TPS will receive consultations by a member of the TPS team pre-, and postoperatively and are monitored frequently, in addition to current standard of care. Patients will be treated according to currently accepted protocols and guidelines. The additional burden for patients is completion of additional questionnaires pre- and postoperative, and after discharge. This will take approximately 20-30 minutes at four moments in six months, whereat for example WHO-DAS 2.0 preoperatively is already standard procedure. Possible benefits for patients are improvement of quality of recovery, prevention of CPSP and avoiding unnecessary opioid prescriptions.

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

1. 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) (8).

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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2021
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL74802.018.20