Research project

Ankle nerve block versus popliteal sciatic nerve block in ambulatory surgery after forefoot surgery – a RCT and follow up study

Short title: Ankle nerve block vs. popliteal sciatic nerve block – a RCT

Dutch title: Enkelblok vergeleken ten opzichte van een popliteaalblok bij voorvoetchirurgie in het chirurgisch dagziekenhuis'

Acronym: PSNSB-ANB-RCT

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1. Summary

Introduction and rationale

Locoregional anesthesia techniques like regional ankle block and single-shot popliteal blocks are reliable tools for effective perioperative pain management in foot and ankle surgery. However there is some evidence that ultrasound guided ankle blocks better maintain motor function and enable faster mobilization which can be advantageous in day-care settings.

Despite the effectiveness of these blocks and improved standardized global pain management, a great number of patients still report very high acute postoperative pain intensity scores. For this reason it is important to further investigate and identify psychological determinants which could explain these differences in pain and could also be useful in order to improve and individualize postoperative pain management.

Design

Randomized controlled single blinded trial.

Setting

ZNA Middelheim, Lindendreef 1, 2020 Antwerpen Belgium and ZNA Jan Palfijn, Lange Bremstraat 70, 2170 Merksem Belgium.

Patients

Two hundred and twenty patients undergoing ankle / foot surgery in day-care settings.

Intervention

Patients will receive an ultrasound-guided ankle block (group A) or an ultrasound-guided popliteal sciatic nerve block – with n. saphenous block (group B) combined with standardized anesthesia and postoperative pain management intrahospital and at home.

Outcome parameters

A. *Primary analysis*

Primary outcome parameter

1. Pain score assessments at home using a Visual Analogue Scale – Pain (VAS-P) during 7 days postoperatively and at day 14 post surgery.

Secondary outcome parameters

1. Functional Recovery Index (FRI) at day 7 and 14 postoperative;
2. Self-reported effective duration of analgesia of locoregional block (within hours after surgery);
3. Participants' subjective satisfaction on a four-point Likert scale regarding placement of the regional block (day 0 = day of surgery);
4. Pain medication adherence at home during 7 days postoperative;
5. Adverse effects including abnormal proprioception, numbness, paraesthesia, neuralgia or motor weakness.

B. *Secondary analysis*

multivariable regression analysis after pooling of the data of group A and group B (or separate analysis on data of group A and/or group B)

Outcome variables: 1**.** pain scores at home using a Visual Analogue Scale – Pain (VAS-P) during 7 days postoperative and at day 14 after surgery; 2. FRI at day 7 and 14 postoperative.

Predictor variables: age, gender, body mass index (BMI), socio-economic status (SES), Charlson co-morbidity index, Medication Quantification Scale (MQS) / medication adherence up to 7 days postoperative, preoperative pain and expected postoperative pain, state anxiety, coping style (need for information), depression, pain catastrophizing and self-efficacy.

Trial registration

At International Standard Randomised Controlled Trial Number:

http://www.IRSCTN.com

2. Introduction and rationale

Foot and ankle surgery is associated with intense postoperative pain, difficult to control with a standard multimodal analgesic approach[1,2] and lasts significantly longer than 24 hours[3,4]. In one study examining pain after forefoot surgery, up to 80% of patients reported severe pain[5].

Ultrasound guided locoregional anaesthesia techniques like popliteal nerve block provide, compared to the more traditional analgesic multimodal techniques, a higher quality of pain relief, a decrease of perioperative opioid consumption and lead to very high satisfaction scores[6-12]. Furthermore additional opioid rescue medication often causes nausea, vomiting and delay in discharge from the hospital[1].

Although ultrasound guided popliteal nerve blocks prove to be very successful in foot and ankle surgery, it is well known they are associated with complications[13,14] which range from 0% up to 5%[15-20]. These complications vary from injection site infection, to sensory (paresthesia, numbness, among others) or motor deficits (weakness, paralysis, permanent motor dysfunction)[13,21]. Recent studies reported short-term complications and short-term rates ranging from 7.2% up to 11%[22,23] and in one study[21] the long-term complication rate following peripheral nerve block during foot and ankle surgery was 4.3% - which was higher than published in current literature[15-20].

The current evolution towards favouring ambulant care leads to the use of techniques that might simplify postoperative treatment and encourages immediate ambulation or fast-track surgery[7]. For this reason regional ultrasound guided ankle blocks might offer such benefits because the use of ultrasound enables us to perform very selective and precise nerve blocks which consequently increases their success rates[1-3,7,24]. This probably causes less complications and renewed interest has appeared.

Delbos *et al.* [7] recently stated that: 1. '*Ultrasound guided ankle blocks are a reliable way to achieve analgesia and anesthesia of the foot and ankle intraoperative anesthesia of the*

foot while maintaining motor function and enabling fast mobilization'; 2. *'more studies comparing popliteal block versus ankle blocks are needed.'*

Undoubtedly, during the last decades a lot of advances have been made in the treatment and understanding of postoperative pain but still a great number of patients suffer from moderate to severe pain[25-27]. Early postoperative pain seems unavoidable, despite intensive and efficient analgesic treatment[28,29].

As we know pain is a complex dynamic and subjective experience with sensory-discriminative, emotional-affective and cognitive-evaluative components[30,31].

Furthermore postoperative outcomes vary considerably between patients who undergo the same kind of surgery (and have the same tissue lesions). Some patients report very high acute postoperative pain intensity scores and some will experience less health-related quality of life improvement whereas others do not[32,33]. There is still a lack of understanding as to what is of influence to explain differences in acute postoperative pain intensity. For this reason it is also essential to gain information about the patient's quality of life and ability to resume normal activity / recovery after discharge from ambulatory surgery and anesthesia[34-36]. Functional recovery of several aspects of the patients' lives is a subjective assessment and therefore it is essential that the assessment should be made from the patients' perspectives[34].

A better understanding of additional predictors of acute postoperative pain and of health related quality of life improvement is essential and will allow anaesthesiologists to implement effective intervention and better perioperative management [27,37].

Postoperative pain is influenced by the patient's age[38,39], gender[27,39] and type of surgery [27], preoperative pain[40] are undoubtedly also influenced by psychological determinants like: 1. expected pain[25]; 2. surgical fear[25]; 3. pain catastrophizing[25,37,40,41]; 4. perioperative state anxiety[27,40,42-44]; 5. presurgical optimism[42]; 6. depression[40,44]; 7. monitor / blunting style – coping style[45,46] etc. Elevated pain intensity scores in trauma patients are

associated with prolonged physical disability[47,48], delayed return to work[47], psychological distress[48,49] and low satisfaction with health care[50].

Postoperative pain, global patient recovery might be influenced by pre-existing psychological determinants[51-53] like catastrophic cognitions about pain and have been shown to be associated with lower ratings of Health Related Quality of Life (HRQoL)[37].

In order to obtain more insight in which determinants could play an important role in postoperative pain intensity scores, we would like to further explore the impact of modifiable factors like general self-efficacy, which has been defined as '*Self-efficacy refers to an individual's belief in his or her capacity to execute behaviors necessary to produce specific performance attainments. Furthermore it reflects confidence in the ability to exert control over one's own motivation, behavior, and social environment'* [54,55]. Low levels of self-efficacy has been proven to negatively affect patients tolerance to acute pain after trauma[56,57] and has been shown to be associated with poor long-term outcomes[47,57]. Further investigating a possible contribution of self-efficacy is important because it has been found to be modifiable and a mediator for improvement in pain and disability. Self-efficacy is an important constructed related to health care and furthermore in rehabilitation [60]

In the current RCT we will focus on patients undergoing a standardized surgical intervention (foot / ankle surgery) in order to minimize variability caused by the surgery itself. Patients will receive either an ankle block or a single-shot popliteal sciatic nerve block (group A and group B). Differences in both, postoperative pain intensity scores and functional recovery will be assessed up to 14 days after surgery. In a second analysis of this research we will further explore possible associations between postoperative pain intensity scores with predictors like: gender, SES, BMI, comorbidity, Medication Quantification Scale (MQS) / postoperative pain medication adherence, state anxiety, coping style (monitor or blunter), pain catastrophizing, depression and general self-efficacy.

3. Aims of the study

A. **[primary analysis]** To assess differences between two ultrasound guided locoregional anesthesia techniques (ankle nerve block - group A and single-shot popliteal sciatic nerve block - group B) after forefoot surgery regarding: 1. postoperative pain intensity levels as assessed with a Visual Analogue Scale Pain (VAS-P) up to 14 days after surgery; 2. self-reported effective duration of analgesia related to the locoregional anesthesia (group A vs. group B); 3. participants' satisfaction (on a four-point Likert scale; 4. Functional Recovery Index (FRI) at day 7 and 14 postoperative (secondary analysis); 5. adherence to postoperative pain medication.

B. **[secondary analysis]** To explain differences in both postoperative pain intensity levels during 7 days and at day 14 (VAS-P) as well as functional recovery at day 7 and at day 14 (FRI) by exploring candidate predictors such as: 1. age, 2. gender; 3. body mass index (BMI); 4. socio-economic status (SES); 5. Charlson Comorbidity Index (CCI); 6. Medication Quantification Scale (MQS); 7. expected postoperative pain; 8. postoperative pain medication adherence during 7 days postoperative; 9. preoperative state anxiety and need for information – monitor/blunting style; 10. pain catastrophizing levels; 11. Hospital Anxiety Depression Scale (HADS); 12. General Self-efficacy Scale (GSE).

4. Methods and materials

Study design

This is a single Randomized Controlled Trial (RCT) comparing two groups of patients which either receive an ultrasound-guided **ankle block (group A)** or an ultrasound-guided **popliteal sciatic nerve block (+ n. saphenous) (group B)**.

This RCT will be approved by the local ethics committee / Institutional Review Board (IRB) and carried out at the ZNA Middelheim, Lindendreef 1, 2020 Antwerpen Belgium and ZNA Jan Palfijn, Lange Bremstraat 70, 2170 Merksem Belgium. Furthermore the study will be registered at https://www.IRSCTN.com and conducted in accordance with the Declaration of Helsinki and the CONSORT guidelines.

Enrolment and data collection

All patients will be approached regarding participation in the study at the surgeon's and / or anesthesia consultation hours and will obtain complete standardized information about the hospital admission and anesthesia procedures and at home pain management.

Inclusion criteria: 1. patients scheduled for ambulatory metatarsal osteotomy / forefoot surgery; 2. American Society of Anesthesiologist (ASA) physical status I-II; 3. written informed consent; 4. good understanding of the Dutch language; 5. without premedication.

Exclusion criteria: 1. refusal to participate; 2. age < 18 years; 3. known preexisting neuropathies; 4. known impaired cognitive function; 5. systemic glucocorticoid administration; 6. pregnancy; 7. chronic use of opioids; 8. intolerance for local anesthetics and non-steroidal anti-inflammatory drugs (NSAID); 9. redo surgery.

All consecutive patients are eligible for inclusion in this study. Patients who initially have given their consent can at all times withdraw without any consequences.

An external investigator not involved in this trial will prepare sequence generation. By picking a computer-generated envelope (opaque, sealed and stapled) participants will be assigned randomly to either **group A – ankle block** or **group B – single-shot popliteal sciatic nerve block (+ n. saphenous)**. Allocation sequence will be concealed from the research nurse and researcher involved in enroling participants.

The sealed randomization envelope will be opened after enrolment and after completing all baseline demographic medical assessments and questionnaires immediately before the intervention.

Demographic data of patients will be collected on the day of admission (standardized interview performed by a research nurse). Demographic data include: 1. gender; 2. age / birthday; 3. length (cm) / weight (kg) (BMI); 4. level of education / (profession) as an indicator of socioeconomic status (SES) classified into three categories: I. no education, elementary school; II. secondary school; III. higher education or university.

Comorbidities: diseases such as hypertension, diabetes mellitus, renal disease, chronic obstructive pulmonary disease (COPD), hyperlipidemia and cardiovascular disease will be recorded. The ***Charlson Comorbidity index*** **(CCI)**[58] will be calculated based on the information regarding diseases / comorbidities. Finally previous surgery will be noted.

Patients will be further classified according to the American Society of Anesthesiologists (ASA) physical status I-II.

Based upon the current analgesic therapy (class, dosage, frequency), the ***Medication Quantification Scale III (MQS-III)***[59], a tool to objectively quantify, will be calculated before the surgical intervention, during 7 days postoperative and at day 14 after surgery. A dichotomous score indicating the use of a specific class of medication (1/0) will be obtained before the treatment. [The MQS III is a method of quantifying different analgesic regimens by evaluating the use of distinct drug classes (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, benzodiazepines, opiates). A

single value is calculated based on a patient's pain medication profile, taking into account dosages, and the types of pain medications prescribed]

Furthermore in the preoperative period patients will be additionally interviewed by using the following assessment tools: 1. Visual Analogue Scale – Pain scores (VAS-P) and Visual Analogue – expected Pain (VAS-exp-P) ; 2. Amsterdam Preoperative Anxiety and Information Scale (APAIS); 3. Hospital Anxiety and Depression Scale (HADS); 4. Pain Catastrophizing Scale (PCS) – (additional state-PCS); 5. Dutch General Self-Efficacy (D-GSE). A full description of these scales will be provided later on in the text.

Concealment of allocation: after picking a computer-generated randomly numbered envelope, patients will be assigned to either **group A** – ankle block or **group B** – single-shot popliteal sciatic nerve block.

After completing all demographic information and questionnaires and in relation to the schedule of surgery the patients will be transported to the holding area in the operating theatre.

Hereafter the patients are transferred to a preparation area designed for performing the echo-guided locoregional block carried out by one of the four anesthesiologists qualified in locoregional anesthesia who participate in this research project.

All usual standard procedures related to surgical intervention under general anesthesia will be applied – there will be no deviation from the ZNA – operation theatre norms.

During this procedure patients will be monitored using ECG, O_2-saturation and non-invasive blood pressure measurement (5 min. interval).

A ultrasound **Sone Site** device and additional nerve stimulation will be used to perform the blocks.

As local anesthetic Ropivacaine 0.5% will be used.

The duration of the block placement as well its degree of technical difficulty should will be recorded by the anesthesiologist (type of quantification using a Likert scale). The ultrasound image during the execution of the block should be graded, e.g. the influence of obesity relating to the technical difficulty to perform the block.

Description of the used ultrasound guided locoregional techniques

General measures

Single blinded selection splits the study population in group A en group B. According the European Society of Anesthesia guidelines during this procedure the patients are monitored using at least a three lead ECG, peripheral pulse oximetry monitoring and non-invasive blood pressure measurement with a minimal of five minutes interval.

Group A: Ultrasound-guided distal peripheral regional ankle block[7]

This technique blocks the terminal branches of the sciatic nerve and the terminal branch of the femoral nerve (the saphenous nerve at this level). It requires the use of a SONO SITE high-frequency linear transducer 13-6 MHz. suitable for such superficial blocks and a 22G Stimuplex Ultra 50 mm needle (B. Braun Medical Inc, Melsungen Germany).

The block consists of five individual paraneural injections depending on the type of surgery.

1. Tibial nerve:

The probe will be placed transversally across the medial aspect of the lower leg, just above the medial malleolus. The needle will be inserted posterior to the probe in the direction of the tibial nerve, which usually lies directly behind the tibial artery. The tibial nerve requires a total of at least 5 ml of Ropivacaine 0.5% to be sufficiently blocked.

2. Deep peroneal nerve;

The probe is placed at the anterior ankle joint on the anterior aspect of the tibia. The puncture side is located at the lateral end of the probe in the in-plane technique or caudal of the long axis of the probe in the out-of-plane technique. The deep peroneal nerve is

usually lateral to the anterior tibial artery, lying on the anterior face of the tibia. The needle is placed toward the deep peroneal nerve, and 5 ml of Ropivacaine 0.5% is injected. If the nerve is difficult to identify, a perivascular injected can be used. Nerve stimulation technique can also be used in addition to ultrasound to confirm the needle position with a typical response from toes.

3. Superficial peroneal nerve:

Probe is positioned on the lateral aspect of the lower leg just proximal to the fibula. The superficial peroneal nerve can be identified between the extensor digitorum longus and peroneus brevis muscle. The nerve can be blocked with 5 ml of Ropivacaine 0.5% either beneath the fascia or just after it has punctured the fascia.

4. Sural nerve:

The sural nerve only innervates lateral plantar aspect in fourth and fifth digit (maybe not mandatory for every type of forefoot surgery). The nerve can be blocked with 5 ml of Ropivacaine 0.5%.

The probe is positioned on the posterolateral aspect of the leg, just proximal to the lateral malleolus.

5. Saphenous nerve:

The probe is placed transversally just proximal and anterior to the medial malleolus, identifying the great saphenous vein. The nerve can be blocked with 5 ml of Ropivacaine 0.5%.

The decision to perform a saphenous nerve block in addition to a sciatic nerve block or a block to the ankle depends on the planned surgery. Although the saphenous nerve block is mandatory for proximal osteotomy, it may not be necessary for more distal osteotomies.

***Group B*: Ultrasound-guided single popliteal sciatic nerve block**[7]

The patient is asked to lay in a prone position and the knee of the operated side is flexed a little and the lower leg is supported with a cushion or pillow to reduce muscle tension. The operator is positioned at the ipsilateral side of the patient and is looking towards the contralaterally placed ultrasound device. Ultrasound guidance at this level is performed using a SONO SITE high-frequency linear transducer 15-6 MHz. and a 22G Stimuplex Ultra 80 mm needle (B. Braun Medical Inc, Melsungen Germany).

The probe is covered with ultrasound gel and placed in the popliteal fossa and shifted towards the head of the patient. The popliteal artery is searched to insure no intravascular infiltration and arterial bleeding. The needle is inserted in-plane from the lateral. The usage of nerve stimulation technique is not routinely used, only if the nerve is not clearly visual under ultrasound and confirmation is necessary. The popliteal sciatic nerve requires a total of 20 ml of local anesthetic - Ropivacaine 0.5% - to be sufficiently blocked.

Saphenous nerve:

The probe is placed transversally just proximal and anterior to the medial malleolus, identifying the great saphenous vein. The nerve can be blocked with 5 ml of local anesthetic (Ropivacaine 0.5%).

The decision to perform a saphenous nerve block in addition to a sciatic nerve block or a block to the ankle depends on the planned surgery. Although the saphenous nerve block is mandatory for proximal osteotomy, it may not be necessary for more distal osteotomies.

After completing the block and having established its effectiveness the patients will be transported to the operating theatre were general anesthesia will applied.

The anesthesia procedure

All patients will receive a standardized preoperative preparation and anesthesia protocol. No premedication will be provided. All patients will receive IV access with IV. Infusion of Ringer-Lactate solution 500 ml. Propofol (max. 3-4 mg/kg IV) along with a low dose of 5 mcg sufentanil (IV) will be used at induction (repeated once if necessary). Maintenance of anesthesia will be carried out using Sevoflurane (VOL% 2-2.5). Further intraoperative pain management consists of: 1. dexamethasone 0.1 mg/kg IV (max 5 mg); 2. paracetamol 15mg/kg IV and ibuprofen 10 mg/kg IV. [If appropriate at the discretion of the attending anesthesiologist a muscle relaxant like rocuronium (0.5 mg/kg IV) can be used].

Standard monitoring

During anesthesia ECG, O_2-saturation, end-tidal CO2, inhalation gas concentration, non-invasive blood pressure measurements (5 min. interval) will be monitored.

Airway management

Laryngeal mask airway (LMA) or endotracheal tube (ET) – spontaneously breathing or mechanical ventilation.

At the end of surgery the patients will be transferred to the Post Anesthesia Care Unit (PACU) and thereafter to the ward.

At the ward the patients receive their diary in which they have to note their pain intensity by using a VAS-P (3 times at the day of surgery). Later they will take home this diary for further assessment of their pain intensity (VAS-P assessment twice a day) and their pain medication consumption in the specially provided daily table, this should be done during the first 7 consecutive days after surgery and at day 14 after surgery. The diary will be given to the patient along with a pre-stamped and self-addressed envelope (Anesthesiology Department Registry ZNA Middelheim, Lindendreef 1, 2020 Antwerpen).

Standardized postoperative pain management at home

Information about pain management at home as well as a prescription will be given to the patient in a standardized way.

The oral pain management will consist of: 1. paracetamol (maw. 60 mg/kg/day); 2. NSAID – ibuprofen (30 mg/kg/day) and as rescue medication tramadol (max 400mg/kg/day) is suggested.

Diary at home – during 7 days + telephone interviews (at day 1 and day 5)

At day 14 = telephone contact FRI and pain assessment.

Also questions related to complications of the performed block: redness, paresthesia, pain at puncture side, residual motor block to be noted in the diary.

Time of onset of pain after surgery to be noted in the diary at home.

Pain medication adherence in the diary during 7 days and asking at day 14 – further quantified by the *Medication Quantification Scale III (MQS-III)*

Overall satisfaction – VAS 100 mmm after 7 day and at day 14.

5. Research instruments

I. Preoperative questionnaires – (predictors)

1. Visual Analogue Scale – Pain scores (VAS-P)[60-64] (attachment 1)

The horizontal VAS-P is a single item and continuous scale of 100 mm in length and is anchored by 2 verbal descriptors, one for each symptom extreme. Verbal descriptor anchors are: 'no pain (score 0) and 'pain as bad as it could be' [or 'worst imaginable pain'] (score 100 – on a 100-mm scale). Respondents are asked to report 'current' pain intensity. Patients will receive a personal diary in which they will be asked to place a line perpendicular to the VAS-P which reflects their pain intensity. The VAS-P will be noted in a diary three times (once preoperative) (interval 4 hours) during the day of surgery and from day one postoperative twice a day (morning after breakfast and in the evening from 8 PM onwards). Higher scores indicate higher pain intensity. Based on distribution analysis of VAS-P score in postsurgical patients[65], pain intensity can be described as: no pain (0 – 4 mm), mild pain (5 – 44 mm), moderate pain (45 – 74 mm) and severe pain (75 – 100). Normative data are not yet available.

Application of the VAS-P requires little training to use and scoring has been found acceptable to patients with a minimal of burden. Test-retest reliability is good but higher among literate (r=.94) compared to illiterate patients (r=.71)[66]. Validity cannot be established in absence of a gold standard in pain assessment[64]. Construct validity with a 5 point verbal descriptive scale and numeric rating scale ranges is good (correlations ranges from .71 – .78 to respectively .62 – .91)[67,68].

Expected postoperative pain – Visual Analogue Scale expected pain (VAS-exp-P) (attachment 2)

During the preoperative period patients are asked to quantify the pain intensity they expect they will suffer postoperatively.

2. Amsterdam Preoperative Anxiety and Information Scale (APAIS)[69] (attachment 3)

The APAIS is a reliable and validated Dutch self-report questionnaire that consists of six questions and has been specifically developed to evaluate preoperative state anxiety and need for information requirement of / coping style in patients undergoing surgery and anesthesia.

The patients' state anxiety (APAIS-state) is assessed by 4 questions: 1. I am worried about the anesthetic; 2. the anesthetic is on my mind continually; 3. I am worried about the procedure; 4. the procedure is on my mind continually.

The patients' need for information (APAIS-information) is assessed by 2 questions: 1. I would like to know as much as possible about the anesthetic; 2. I would like to know as much as possible about the procedure. The anxiety part correlates strongly (r = 0.74) with the state part of the Spielberger State-Trait Anxiety Inventory (STAI)[70] and the correlation with the information items and the State-STAIC was low (r = 0.16).

Both the APAIS-state and APAIS-information scales – each question can be answered with response categories on a 5-point Likert scale. The APAIS-state subscale range from 4 – 20 and the APAIS-information subscale range from 2 – 10. A value ≥ 13 on the APAIS-state decreases the rate of false-positives.

APAIS-information: a score between 2 – 4 means no/little information need; 5 – 7 average information need and scores between 8 – 10 a high information need. A score ≥ 5 can be interpreted as having a positive attitude toward receiving information. The APAIS is very easily and quickly to complete. The APAIS will be filled in only once preoperatively on the day of surgery.

3. Hospital Anxiety and Depression Scale (HADS)[71,72] (attachment 4)

The HADS was developed in 1983 to identify possible anxiety disorders and depression among patients in nonpsychiatric hospital clinics. Evidence exists for a two-factor solution in accordance with the HADS subscales for anxiety (HADS-A)

and depression (HADS-D) – correlations varied from .40 to .74 - mean .56. Cronbach's alpha for the HADS-A varied from .068 to .93 (mean .83) and for the HADS-D from .67 to .90 (mean .82). An optimal balance between sensitivity and specificity (for both 0.80) has been achieved at a score of ≥ 8 on the HADS-A and HADS-D. The total HADS scale showed a good balance between sensitivity and positive predictive value (PPV) in identifying a psychiatric disorder. Homogeneity and test-retest reliability of the total scale and the subscales are good. The dimensional structure and reliability of the HADS is stable across medical settings and age groups. The HADS consists of 2 (7-items) subscales measuring anxiety (HADS-A) and depression (HADS-D) in patients in hospital setting. Each item can be answered in a Likert from 0 to 3 form. Subscales range from 0 – 21. Higher scores implicate higher levels of anxiety and depression. The HADS will be filled in only once preoperatively on the day of surgery.

4. Pain Catastrophizing Scale (PCS)[41,73,74] (attachment 5)

The Pain Catastrophizing Scale (PCS) is a 13-item scale to assess catastrophic thinking associated with pain. Pain catastrophizing is related to a more intense pain experience and emotional distress in more exaggerated terms compared to a an average person. These persons tend to ruminate over it more, f.i. the item 'I kept thinking this is terrible', to feelings of more helplessness about the experience, f.i. the item 'I thought it was never going to get better' and by feelings of excessive magnification, f.i. the item 'I´m afraid that something serious might happen'. Participants are asked to rate the frequency on the 13 thoughts or feelings when they are in pain. These ratings are made on a 5-point Likert scale with the following end-points: 0 = not at all and 4 = all the time. A total score is computed and 3 subscale scores assessed rumination, helplessness and magnification. The PCS is a reliable and valid measure for catastrophizing [75]. Subscales of the PCS have been shown to have adequate to high internal

consistency (Cronbach alpha's ranges: total PCS = 0.87, rumination = 0.87, magnification = 0.66, and helplessness = 0.78).

The PCS scale has also been validated (not published) in Dutch by Crombez *et al* [76] and the psychometric characteristics were further investigated by Van Damme *et al* [77,78]. The Dutch questionnaire has a good reliability (ICC: R = 0.73) and a good construct / content validity. Internal consistency ranges from Cronbach alpha's between 0.70 and 0.93. PCS will be filled in only once preoperatively on the day of surgery.

5. Dutch General self-efficacy scale (DGSE)[79] (attachment 6)

Self-efficacy can be defined as: '*Beliefs in one's capabilities to mobilize the motivation, cognitive resources, and courses of action needed to meet given situational demands*' [57]. General self-efficacy covers several domains of human functioning in people [82] and several studies have shown that higher scores on self-efficacy were associated with less depressive feelings, with less perceived pain intensity, with higher self-reported health, satisfaction and more physical activity. Self-efficacy is an important constructed related to health care and furthermore in rehabilitation [60].

The General Self-efficacy Scale (GSE) consists of 10 items and has been translated into Dutch by Teeuw *et al*[83]. In one study which included GSE from 25 countries reliability ranged from .75 to .91 (Cronbach α)[84]. Principal component and additional confirmatory factor analyses identified one-dimensionality[60,84,85]. The 10 items are each rated using four response categories: 1. not at all; 2. hardly true; 3. moderately true; 4. exactly true. The summed score ranges from 10 to 40. Higher scores are related to higher/better self-efficacy.

II. Postoperative questionnaires – outcomes variables

1. VAS pain scale

See above p. 14.

Postoperative pain intensity levels with VAS-P: day 0 the first 7 days at home (twice/day) and once at day 14.

2. Self-reported effective duration of analgesia (Day 0), self-reported effective duration of analgesia (to be noted in the patient's diary at home), representing participants' positive response to treatment of the locoregional block.

3. Participants' satisfaction on a four-point Likert scale (Day 7), in which they described their level of satisfaction by using a quantitative value (i.e., 1 [poor], 2 [average], 3 [good], and 4 [very good]).

4. Functional Recovery Index at day 7 and 14 (FRI)[34] (attachment 9)

The FRI has been developed to assess postoperative discharge functional recovery for ambulatory surgical patients that and consists of 14 questions grouped under 3 factors. Each item is scored from 0 to 10, with 0 no difficulty and 10 extreme difficulty with the activity. The 3 factors are summated for a total score. A grand score can be calculated and equals = (total of all scores) X 14/ number of answered. If patient do not normally perform such activities, e.g., driving, the patient has to choose not applicable (NA). The same applies when patients are instructed by the surgeon not to perform the activity. The FRI has an excellent reliability and good validity. Internal consistency for the 3 factors (pain and social activity, lower limb activity, and general physical activity) is as follows: Cronbach 0.90, 0.89, and 0.86, respectively. Interrater reliability was 0.99. Convergent validity for FRI versus verbal rating scale pain score was 0.76. Discriminant validity testing showed that the type of surgery was significant and that intermediate

(0.138) and major surgery (0.337) were associated with higher FRI scores than minor surgery. The FRI is assessed at day 7 and at day 14 postoperative.

6. Statistical analysis

Sample size calculation

With an estimate of both within group standard deviation and the sample size equation, the number of patients required can again be solved as per a parallel group study:

$$n = \frac{2\left(Z_{1-\beta} + Z_{\alpha/2}\right)^2 \sigma_w^2}{d^2}$$

$$n = \frac{2(1.2816 + 1.9600)^2 \cdot 3^2}{1^2}$$

$$n = 189$$

When assuming a post-randomization attrition rate of 20%

n=226

When accepting:

α = 0.05 (type i error);

β = 0.1 (type ii error), and 1- β=0.9t (power);

σ = 3, (standard deviation), assumed to be equal for both groups;

d = 1 (the difference in VAS score between that needs to be detected between the treatment groups)

Note: the following assumptions for the sample size calculation were taken into account: 1. the results of a previous study of Stefani *et al* [2], which obtained mean postoperative VAS scores ± SD – on a continuous VAS scale of 100 mm – equal to 3.8 ± 2.25 (regional ankle block) vs. 5.1 ± 2.55 (control group); 2. that a relevant clinical difference in VAS scores needed to be detected is a difference VAS of 1 or 10 mm; 3. assuming equal variance corresponding to a SD of 3 VAS units or 30 mm.

The primary outcome, absolute VAS-P pain score ratings will be obtained at: 1. the day of surgery (3 times) directly postoperative the day of surgery; 2. at home twice a day during 7 days; 3. VAS-P pain scores at home at day 14**.**

The secondary outcomes: 1. FRI at day 7 and at day 14; 2. self-reported effective duration of analgesia (to be noted in the patient's diary at home), representing participants' positive response to treatment; 3. participants' satisfaction on a four-point Likert scale, in which they describe their level of satisfaction by using a quantitative value (i.e., 1 [poor], 2 [average], 3 [good], and 4 [very good]) at day 7; 4. medication consumption, which is monitored at home twice a day during 7 days and at day 14 which will be further quantified by using the Medication Quantification Scale version III (MQS III) ratings as well as a dichotomous score to indicate whether or not (yes/no or 1/0) a participant is on a specific analgesic or class of medication (paracetamol, NSAIDs, tramadol, opioids); 5. adverse effects including abnormal proprioception, numbness, paraesthesia, neuralgia, and motor weakness.

Statistical Analyses

Comparisons of mean age, body mass index, and the MQS III scores between the ankle block (group A) and the single-shot popliteal block (group B) will be assessed by using the two-tailed t test for independent samples. Baseline participant characteristics (sex, presence of comorbidities) will be compared between the treatment groups by using the Fisher exact test.

After data acquisition will be complete, the VAS-P, VAS-exp-P, APAIS, HADS, PCS, D-GSE and their respective subscales, will be compared between treatment group A and B at the different times of assessment using two-tailed t-tests for independent samples. Furthermore after data acquisition VAS-P, VAS-exp-P, FRI, APAIS, HADS, PCS and D-GSE and their respective subscales, will be compared between group A and group B treatment groups at the different times of assessment (baseline and at follow-up 7 days and at day 14) by using Generalized Estimating Equations (GEEs)[80]. GEEs represent an

extension of the generalized linear models (GLM) with the ability to model a wide variety of correlation patterns between the repeated measures. For each of the investigated categories, the Holm-Šidak approach will be used for post hoc pairwise comparison to test for differences in the mean VAS-P and other scores between the popliteal and ankle groups and within (over time) these treatment groups.

The effective duration of participants' positive response to treatment will be compared between group A and group B treatment arms by using Kaplan-Meier survival (time-to-event) analysis. Within this context survival times represent the follow-up time from the establishment of block until the occurrence of the event of interest, i.e., 'when the perceived beneficial effect of treatment becomes unsatisfactory'. Participants who will not experience this particular event during follow-up will have their survival times censored. The log rank test will be used to test whether the survival distributions of group A and group B treatment groups are different.

Satisfaction scores between group A and group B will be compared by using a multilevel mixed-effects ordered logistic regression. In the present investigation the ordered categorical response represented a person's satisfaction, rated on a four-point Likert scale (1 [poor], 2 [average], 3 [good], and 4 [very good]).

The MQS III ratings before treatment and at follow-up at 7 days and at day 14 after the intervention will be compared by using the paired t test. The use of a specific analgesic or class of medication before therapy and at day 14 after the intervention will be compared with the McNemars' test on paired proportions. MQS III ratings for a given time of assessment (before treatment or at day 14 after the intervention) will be compared between treatment group A and group B by using the two-tailed t test for independent samples. The use of a specific class of medication for a given time of assessment (before intervention or at day 14 after the intervention) will be compared between treatment group A and group B by using a Fisher exact test.

Secondary analysis: Generalized Linear Regression Analysis

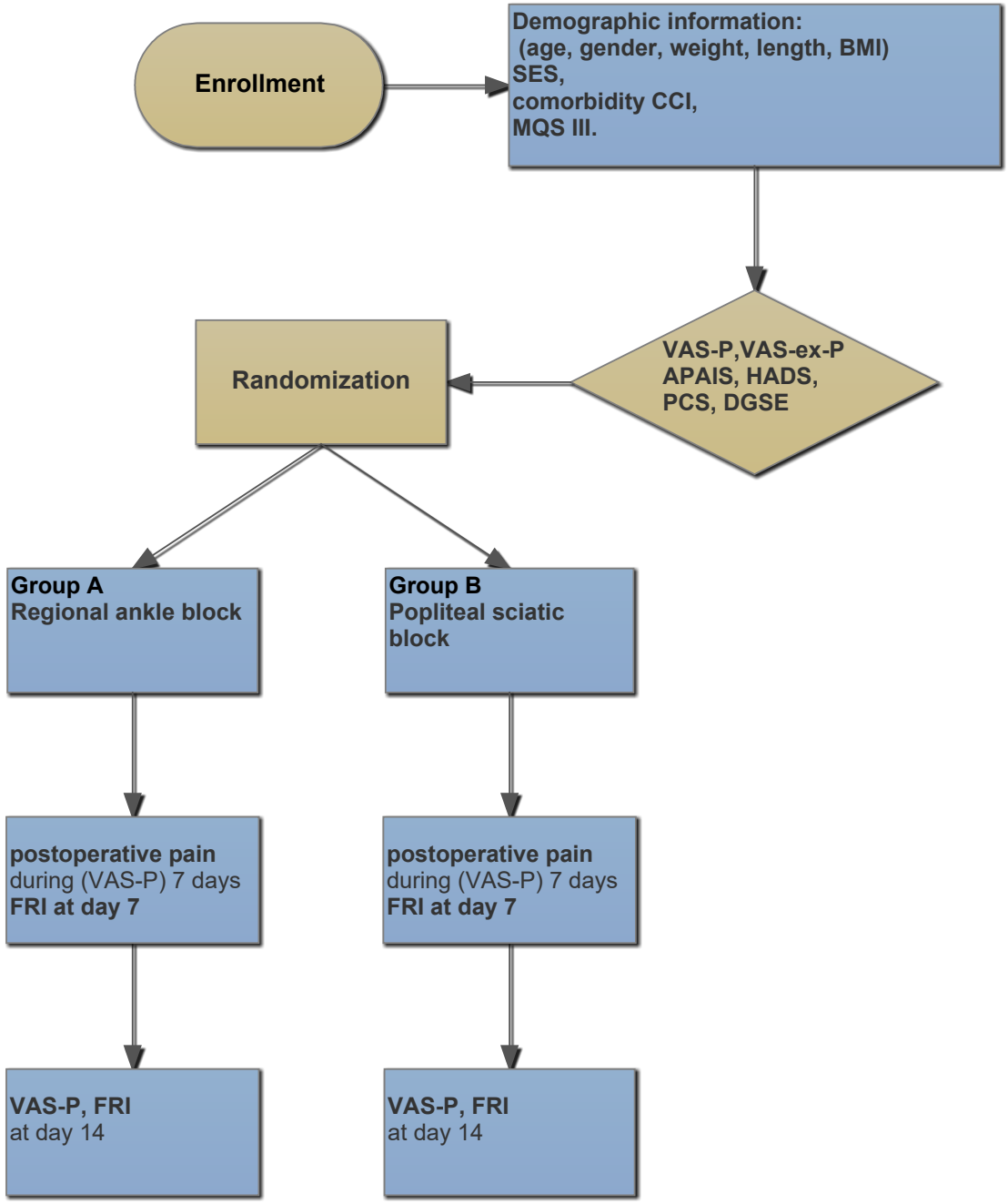
Furthermore multivariable statistical models and selection criteria such as partial R^2 AIC (Akaike information criterion) will be used to assess whether potential characteristics can be associated with the postoperative outcome scores (postoperative pain scores) i.e. VAS-P beyond the efficacy of the type of block. Possible covariables (effect modifiers or predictors) for inclusion were based on existing knowledge and clinical judgment. The associations of the following covariables with the outcome of intervention will be analysed: 1. participants' age (years); 2. sex (males=0, females=1); 3. body mass index ($kg \cdot m^{-2}$); 4. arterial hypertension (Y/N or 1/0); 5. preoperative pain (VAS-P); 6. expected postoperative pain (VAS-exp-P); 7. state anxiety and need for information (APAIS); 8. HADS (total score or depressive (Y/N or 1/0) and/or anxiety disorder (Y/N or 1/0)); 9. opioid use before intervention (Y/N or 1/0); 10. modality of locoregional block (popliteal block=0 and ankle block=1); 11. PCS (total score); 12. D-GSE (total score).

Covariables associated with the outcomes on univariable analysis ($P<0.25$) will be included in a multivariable statistical model. We then sequentially excluded variables and terms from this initial multivariable model, using a stepwise backward-elimination procedure. The aim is to seek the most parsimonious model (smallest number of independent variables) that still explains the outcome. Covariables that are correlated or highly collinear will be excluded. The following outcomes will be explored: 1) the proportion of participants with a successful outcome (≥50% reduction of pre-intervention VAS rating at 7 days and 14 days after the intervention), using a logistic model; 2) the perceived duration of therapeutic effect, using a Cox proportional hazards model; 3) participant satisfaction, using a mixed-effects ordered logistic regression model; and 4) the reduction in analgesic consumption, measured by the MQS III score.

Normality of distribution for the data sets with continuous variables will be checked by visual inspection of the distribution and by using the Shapiro-Wilk and Kolmogorov-

Smirnov tests. Statistical significance will be set at the 0.05 probability level. Data analysis will be performed with **R version 4.0.4** (*R* Foundation for *Statistical* Computing, Vienna, *Austria*) or Stata version 15 (StataCorp, College Station, TX).

7. Flowchart



BMI: Body Mass Index; SES: socioeconomic status; CCI: Charlson Comorbidity index ; MQS-III: Medication Quantification Scale III (MQS-III); VAS-P: Visual Analogue Scale Pain; VAS-ex-P: expected postoperative pain; APAIS: Amsterdam Preoperative Anxiety Information Scale; HADS: Hospital Anxiety and Depression Scale; PCS: Pain Catastrophizing Scale; DGSE: Dutch General Self-Efficacy scale; FRI: Functional Recovery Index

8. Ethical considerations

This study will be conducted according to the principles of the Declaration of Helsinki (version of 2008, updated 23/11/2017). Prior to patient enrolment, the protocol must be approved by the ZiekenhuisNetwerkAntwerpen (ZNA) Institutional Review Board (IRB) (Chair: prof. Dr. P.P. De Deyn - ZNA Koningin Paola Kinderziekenhuis, P4, Route 34, Lindendreef 1, 2020 Antwerpen).

9. Administrative aspects, monitoring & publication

1 Handling and storage of data and documents

By answering the questions of the questionnaires, patients give consent to use this data for the study. Participants data will be handled anonymously, using coding for each individual participant of the study. Each participant will have their own CRF number. The key to the code for each participant will be held by the principal investigator. Only study personnel involved with the specific parent will have access to the anonymous personal data. We will store data following the law: study data have to be stored for 25 years. Anonymous data will be analysed in R4.0.4 and Stata version 15.

2 Monitoring and Quality Assurance

Not applicable.

3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited IRB has been given. All amendments will be notified to the IRB.

All substantial amendments will be notified to the IRB and to the competent authority.

Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

4 Temporary halt and (prematurely) end of study report

Not applicable.

5 Public disclosure and publication policy

The results of the study will be published in a medical journal.

6 Structured risk analysis

Not applicable.

10. Attachments

1. VAS-P (visuele analoge schaal - pijn)

Plaats een verticale streep op de lijn die het best de ernst van uw pijn weergeeft.

0 **100**

geen enkele pijn **meest voorstelbare pijn**

score range 0 – 100 mm

2. VAS-exp-P (visuele analoge schaal - pijn)

Plaats een verticale streep op de lijn en geef de pijnintensiteit weer die u verwacht na de ingreep

0 **100**

geen enkele pijn **meest voorstelbare pijn**

score range 0 – 100 mm

3. Amsterdam Preoperative Anxiety and Information Scale (APAIS)

	Score van 1 tot 5				
1. Ik ben bezorgd over de narcose	**1**	**2**	**3**	**4**	**5**
2. Ik denk constant aan de narcose	**1**	**2**	**3**	**4**	**5**
3. Ik wil zo veel mogelijk weten over de narcose	**1**	**2**	**3**	**4**	**5**
4. Ik ben bezorgd over de operatie	**1**	**2**	**3**	**4**	**5**
5. Ik denk constant aan de operatie	**1**	**2**	**3**	**4**	**5**
6. Ik wil zoveel mogelijk weten over de operatie	**1**	**2**	**3**	**4**	**5**

4. Hospitaal angst en depressie schaal

Het is bekend dat emoties bij de meeste ziektes een belangrijke rol kunnen spelen.

Deze vragenlijst dient als hulpmiddel om te weten te komen hoe u zich voelt. Lees iedere vraag en onderstreep het antwoord dat het beste weergeeft hoe u zich **gedurende de laatste week** gevoeld heeft. Denk niet te lang na over uw antwoord. Uw eerste reactie op elke vraag is waarschijnlijk betrouwbaarder dan een lang doordacht antwoord.

1. Ik voel me gespannen

☐ Meestal ☐ Vaak ☐ Af en toe ☐ Soms

2. Ik geniet nog steeds van de dingen waar ik vroeger van genoot

☐ Zeker zo veel ☐ Niet zoveel als vroeger ☐ Weinig ☐ Haast helemaal niet

3. Ik krijg een soort angstgevoel alsof er elk moment iets vreselijks zal gebeuren

☐ Heel zeker en vrij erg ☐ Ja, maar niet zo erg ☐ Een beetje, maar ik maak me er geen zorgen over ☐ Helemaal niet

4. Ik kan lachen en de dingen van de vrolijke kant zien

☐ Net zoveel als vroeger ☐ Niet zo goed als vroeger ☐ Beslist niet zoveel als vroeger ☐ Helemaal niet

5. Ik maak me vaak ongerust

☐ Heel erg vaak ☐ Vaak ☐ Af en toe maar niet te vaak ☐ Alleen soms

6. Ik voel me opgewekt

☐ Helemaal niet ☐ Niet vaak ☐ Soms ☐ Meestal

7. Ik kan rustig zitten en me ontspannen

☐ Zeker ☐ Meestal niet ☐ Vaak ☐ Helemaal niet

8. Ik voel me alsof alles moeizamer gaat

☐ Bijna altijd ☐ Heel vaak ☐ Soms ☐ Helemaal niet

9. Ik krijg een soort benauwd, gespannen gevoel in mijn maag

☐ Helemaal niet ☐ Soms ☐ Vrij vaak ☐ Heel vaak

10. Ik heb geen interesse meer in mijn uiterlijk

☐ Zeker ☐ Niet meer zoveel als ik zou moeten ☐ Waarschijnlijk niet zoveel ☐ Evenveel interesse als vroeger

11. Ik voel me rusteloos en voel dat ik iets te doen moet hebben

☐ Heel erg ☐ Tamelijk veel ☐ Niet erg veel ☐ Helemaal niet

12. Ik verheug me van tevoren al op dingen

☐ Net zoveel als vroeger ☐ Een beetje minder dan vroeger ☐ Zeker minder dan vroeger ☐ Bijna nooit

13. Ik krijg plotseling gevoelens van panische angst

☐ Zeer vaak ☐ Tamelijk vaak ☐ Niet erg vaak ☐ Helemaal niet

14. Ik kan van een goed boek genieten, of van een radio- of televisieprogramma

☐ Vaak ☐ Soms ☐ Niet vaak ☐ Heel zelden

5. Pijncatastroferenschaal

Geautoriseerde Nederlandstalige vertaling G. Crombez en J. Vlaeyen

Denk aan uw huidige episode met pijn en geef aan in welke mate een aantal gedachten of gevoelens bij u opkomt. Zet een rondje om het cijfer dat hierop van toepassing is.

Items: **Als ik pijn heb...**	**Helemaal niet**				**Altijd**
1. Vraag ik mij voortdurend af of de pijn wel zal ophouden.	0	1	2	3	4
2. Voel ik dat ik zo niet verder kan.	0	1	2	3	4
3. Is dat verschrikkelijk en denk ik dat het nooit beter zal worden.	0	1	2	3	4
4. Is dat afschuwelijk en voel ik dat de pijn mij overweldigd	0	1	2	3	4
5. Voel ik dat ik het niet meer uithoud.	0	1	2	3	4
6. Word ik bang dat de pijn erger zal worden.	0	1	2	3	4
7. Blijf ik denken aan andere pijnlijke gebeurtenissen.	0	1	2	3	4
8. Verlang ik hevig dat de pijn weggaat.	0	1	2	3	4
9. Kan ik de pijn niet uit mijn gedachten zetten.	0	1	2	3	4
10. Blijf ik eraan denken hoeveel pijn het wel doet.	0	1	2	3	4
11. Blijf ik denken hoe graag ik zou willen dat de pijn ophoudt.	0	1	2	3	4
12. Is er niets dat ik kan doen om de intensiteit van de pijn te verminderen.	0	1	2	3	4
13. Vraag ik mij af of er iets ernstigs kan gebeuren.	0	1	2	3	4

6. Zelfredzaamheidschaal Nederlands

Hieronder volgen 10 stellingen over hoe u in het algemeen denkt en wat u doet. Zou u aan willen geven in hoeverre u het oneens of eens bent met deze stellingen? Wil u daartoe voor alle stellingen het antwoord aankruisen dat OP DIT MOMENT op u het meest van toepassing is.

	Volledig onjuist	Nauwelijks juist	Enigszins juist	Volledig juist
1. Het lukt me altijd moeilijke problemen op te lossen, als ik er genoeg moeite voor doe.	☐	☐	☐	☐
2. Als iemand mij tegenwerkt, vind ik toch manieren om te krijgen wat ik wil.	☐	☐	☐	☐
3. Het is voor mij makkelijk om vast te houden aan mijn plannen en mijn doel te bereiken.	☐	☐	☐	☐
4. Ik vertrouw erop dat ik onverwachte gebeurtenissen doeltreffend aanpak.	☐	☐	☐	☐
5. Dankzij mijn vindingrijkheid weet ik hoe ik in onvoorziene situaties moet handelen.	☐	☐	☐	☐
6. Ik kan de meeste problemen oplossen als ik er de nodige moeite voor doe.	☐	☐	☐	☐
7. Ik blijf kalm als ik voor moeilijkheden kom te staan omdat ik vertrouw op mijn vermogen om problemen op te lossen.	☐	☐	☐	☐
8. Als ik geconfronteerd wordt met een probleem heb ik meestal meerdere oplossingen.	☐	☐	☐	☐
9. Als ik in een benarde situatie zit, weet ik meestal wat ik moet doen.	☐	☐	☐	☐
10. Wat er ook gebeurt, ik kom er wel uit.	☐	☐	☐	☐

7. Gegevens in verband met de anesthesie

Duur van de anesthesie en toegediende medicatie (standaardprotocol) en het bijhouden van alle relevante gegevens/gebeurtenissen tijdens de anesthesie en in de postanesthesie zorgafdeling (PAZA)

Datum van de ingreep:

Type van de ingreep:

Lateralisatie: links rechts

Zenuwblok (gecodeerd):

Type anesthesie (aanduiden)

Algemene narcose	Sedatie
propofol inductie met volatiele gasonderhoud	*Propofol TCI*
☐	☐

Extra toegediende intraveneuze medicatie

Sufentanil	5 µg	Ja / Nee	Dosis
Dexamethasone	5 mg	Ja / Nee	Dosis
Cefazoline	2 g	Ja / Nee	Dosis

Toegediende pijnstilling

Paracetamol	1000 mg	Ja / Nee	Dosis
Ibuprofen	max 600 mg	Ja / Nee	Dosis
Extra sufentanil		Ja / Nee	Dosis

Rescue medicatie op PAZA/ recovery

Dipidolor	*getitreerd*	Ja / Nee	Dosis
Tramadol / Litican	100 mg / 50 mg	Ja / Nee	Dosis

8. Pijnmetingen postoperatief

DAG 0 (dag van de operatie)

VAS-P (visueel analoge schaal - pijn)

's Ochtends

0 **100**

geen enkele pijn **meest voorstelbare pijn**

score bereik 0 – 100 mm

's Avonds

0 **100**

geen enkele pijn **meest voorstelbare pijn**

scorebereik 0 – 100 mm

Duur tot het uitwerken van het blok:

Pijnmedicatie gebruik

Paracetamol 1000 mg	max 4x/d	Ja / Nee	Aantal: 0 1 2 3 4
Ibuprofen 600 mg	max 3x/d	Ja / Nee	Aantal: 0 1 2 3
Tramadol Litican	100 mg / 50 mg	Ja / Nee	Aantal: 0 1 2 3 4

DAG 1 (dag na de operatie)

VAS-P (visuele analoge schaal - pijn)

's Ochtends

0 **100**

geen enkele pijn **meest voorstelbare pijn**

score bereik 0 – 100 mm

's Avonds

0 **100**

geen enkele pijn **meest voorstelbare pijn**

score bereik 0 – 100 mm

Duur tot het uitwerken van het blok:

Pijnmedicatie gebruik

Paracetamol 1000 mg	max 4x/d	Ja / Nee	Aantal:	0	1	2	3	4
Ibuprofen 600 mg	max 3x/d	Ja / Nee	Aantal:	0	1	2	3	
Tramadol Litican	100 mg / 50 mg	Ja / Nee	Aantal:	0	1	2	3	4

9. Postoperative Functional Recovery Index (FRI)

6.1 Factor 1: Pijn en sociale activiteiten

Heeft u sinds uw operatie moeilijkheden ervaren met een van de volgende:

1. het werk opvatten

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

2. Familie en vrienden **bezoeken**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

3. Voor familieleden **zorgen**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

4. Met de **auto rijden**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

5. Bescheiden **fysieke activiteit uitvoeren,** zoals een tafel verzetten of een stofzuiger duwen

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

6. Boodschappen opheffen of dragen

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

7. Sinds uw operatie, heeft u **last van pijn?**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing

Helemaal geen moeilijkheden — Extreme moeilijkheden

6.2 Factor 2: Activiteit in de lagere ledematen

1. Binnenshuis en rond het huis wandelen

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing

Helemaal geen moeilijkheden — Extreme moeilijkheden

2. In **een stoel gaan zitten en opstaan uit een stoel**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing

Helemaal geen moeilijkheden — Extreme moeilijkheden

3. De **trap opgaan**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing

Helemaal geen moeilijkheden — Extreme moeilijkheden

4. Buigen, door de knieën gaan, hurken

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing

Helemaal geen moeilijkheden — Extreme moeilijkheden

6.3 Factor 3: Algemene fysieke activiteit

Hebt u sinds uw operatie moeilijkheden ervaren met een van de volgende:

1. Een **bad of douche nemen**/uzelf wassen

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

2. U **aankleden**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

3. **Neerliggen**

0	1	2	3	4	5	6	7	8	9	10	Niet van toepassing
Helemaal geen moeilijkheden											Extreme moeilijkheden

Global Summary of parameters

Outcome parameters

1. *Visual Analogue Scale PAIN (VAS-P) directly postoperative*

*VAS-P at **home twice a day** during 7 days and VAS-P at day 14*

2. *FRI at day 7 and day 14*

Predictor variables

1. *age*
2. *gender*
3. *SES*
4. *BMI*
5. *CCI*
6. *MQS*
7. *VAS-exp-Pain*
8. *APAIS state = range (4 – 20)*

   APAIS information = range (2 – 10)
9. *HADS anxiety range (0 – 21), depression range (0 – 21)*
10. *PCS range (0 – 52)*
11. *DGSE (0 – 40)*

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