Peri-surgical observation of nociceptive thresholds during total knee arthroplasty for association with persisting post-surgical pain: an explorative study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40450

Source
ToetsingOnline

Brief title
Peri-surgical observation of nociceptive thresholds

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
Persisting post-surgical pain

Health condition

Persisterende post-operatieve pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: STW

Intervention

Keyword: Nociceptie, Persisting post-surgical pain

Outcome measures

Primary outcome

Persistent post-surgical pain (PPSP)

eQST

o Electrical pain threshold (ePT) [mA]

o Electrical pain tolerance threshold (ePTT) [mA]

Nociceptive Perception thresholds (NPT)

o Stimulus amplitude [mA]

o Responses to stimuli (perceived/not perceived)

o Stimulation time [s]

Secondary outcome

Pain intensity (NRS)

McMaster Universities Osteoarthritis Index (WOMAC)

o Pain scale

o Stiffness scale

o Functional scale

Knee Society Score (KSS)

o Functional scale

Study description

Background summary

Total knee arthroplasty (TKA) often produce severe persistent post-surgical pain (PPSP), and in some cases, chronic pain. While the acute pain postpones the early recovery, the chronic pain seriously restricts an individual*s quality of life, and also increases costs of global health care and absenteeism at work. Central sensitization plays a major role in the development of PPSP. Sensitization is characterized by generalized hyperalgesia and can be detected by means of a decrease in (electrical) pain threshold. Recently, a pilot study showed that pre-surgical electrical pain tolerance thresholds (ePTT) have predictive value for PPSP in abdominal surgery patients. Other pilot studies suggest that, in addition to ePTTs, electrical nociceptive perception thresholds (eNPTs), when tracked over a short period of time (e.g. 25 minutes) can be expected to be able to observe changes in peripheral and/or central mechanisms in more detail than regular EPTs. Results after TKA show similar persisting pain incidences as after abdominal surgery. Therefore, these patients are a suitable population to study the generalizability of the results found in previous studies.

Study objective

The main objective of this study is to investigate the predictability of persisting post-surgical pain (PPSP) after TKA using electrical quantitative sensory testing (eQST) and nociceptive perception thresholds (NPT) in combination with a pre-surgical conditioning pain modulation (CPM) paradigm. The secondary objectives of this study are to investigate (1) the effect of TKA on stimulus specific changes in NPT, and (2) the correlation between eQST versus NPT and PPSP.

Study design

Mono-centre prospective observational study

Study burden and risks

This is a prospective exploratory study without experimental intervention. After signing the informed consent form, patients will have four visits at the Radboud University Nijmegen Medical Centre. The medical centre visits are planned on days where patients are already scheduled for a regular visit. Pain thresholds, pain tolerance thresholds, and nociceptive perception thresholds

will be measured using eQST and NPT equipment, and several questionnaires will be filled in by all patients. All patients will undergo a cold pressor test during the baseline measurement as well. Moreover, patients will also receive two telephone calls including the relevant questionnaires. The participating patients will obtain no direct personal benefit.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients scheduled for total knee arthroplasty.

Exclusion criteria

- Patient*s refusal
- Pre-existing neurological or psychiatric illnesses
- Chronic pain syndromes
- Alcohol or drug abuse
- Suspected possibility of delirium
- Difficulties in communication
- Rheumatoid arthritis
- Revision knee surgery or participation in another study
- Pre-surgicaloperative ASA score >3

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-01-2015
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

ID: 26714
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47455.091.14
Other	Volgt na goedkeuring METC
OMON	NL-OMON26714