Perisurgical observation of nociceptive thresholds during total knee arthroplasty for association with persisting postsurgical pain: an explorative study

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26714

Source
NTR

Health condition

Total knee arthroplasty, persisting pain, chronic pain

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: STW/NWO

Intervention

Outcome measures

Primary outcome

- Persistent postsurgical 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

Background of the study:
Total knee arthroplasty (TKA) often produce severe persistent postsurgical 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 presurgical 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.

Objective of the study:
The main objective of this study is to investigate the predictability of persisting postsurgical pain (PPSP) after TKA using electrical quantitative sensory testing (eQST) and nociceptive perception thresholds (NPT) in combination with a presurgical 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:
Monocentre prospective observational study

Study design

Preoperative: baseline measurement at -35 to -7 days

Postoperative: days 2, 42, 84, 168, and 365

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Patients scheduled for total knee arthroplasty.

Exclusion criteria

- Patient’s refusal

- Preexisting 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

- Presurgicaloperative ASA score >3

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-02-2015
Enrollment:	40
Type:	Unknown

Ethics review

Positive opinion
Date: 14-01-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40450
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4710
NTR-old	NTR4981
CCMO	NL47455.091.14
OMON	NL-OMON40450

Study results

Summary results
N/A