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The difference between the documented and perceived adherence to the pain management protocol in patients undergoing lower limb amputation

Submission date
17/01/2021

Recruitment status
No longer recruiting

Registration date
09/02/2021

Overall study status
Completed

Last Edited
05/04/2022

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the Netherlands, approximately 3,300 lower limb amputations are performed annually. An amputation is a major intervention, which is associated with severe postoperative pain. Chronic postsurgical pain is only partly understood, difficult to treat and the effectiveness of treatment is limited. The severity and duration acute postoperative pain is associated with the risk of chronic pain. Preventive treatment should take place in the preoperative, intraoperative and in the first week of the postoperative phase with the aim of preventing long-term sensitization of the spine by blocking or modulating the nociceptive input after peripheral nerve damage. A perioperative pain management protocol for amputation has been introduced in the UMCG. This protocol describes the items and associated interventions of pain management that should be performed during the perioperative period of amputation. This protocol should be followed unless there are contra-indications in specific parts of the protocol.
The study aims to discover how this protocol was followed by patients.

Who can participate?
Patients who underwent amputation of the lower limb at the University Medical Center Groningen (Netherlands) (June 28, 2017 - February 1, 2020)

What does the study involve?
All patient records were analyzed to determine adherence to the perioperative pain management protocol (PPMP). To identify the perceived adherence to the PPMP a survey was also conducted among involved physicians.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
December 2019 to October 2020

Who is funding the study?
University Medical Center Groningen (Netherlands)

Who is the main contact?
Prof André P. Wolff, a.p.wolff@umcg.nl

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
201900820

Study information

Scientific Title
Discrepancy between the documented and perceived adherence to the perioperative pain management protocol in patients undergoing lower limb amputation. A retrospective observational study

Study objectives
The adherence to the perioperative pain management protocol in patients who underwent a lower limb amputation is high

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 10/12/2019, University Medical Center Groningen Institutional Review Board (PO Box 30 001, 9700 RB, Groningen, The Netherlands; +31 503614204; metc@umcg.nl), ref: METc 201900820

Study design
Retrospecitve observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients who underwent a lower limb amputation

Interventions
Between June 1, 2017 and February 29, 2020, 153 lower limb amputations were performed. All patient records were analyzed retrospectively to determine the documented adherence to the perioperative pain management protocol (PPMP). To identify the perceived adherence to the PPMP a survey was also conducted among involved physicians.

Intervention Type
Other

Primary outcome(s)
1. Documented adherence by patients to the perioperative pain management protocol measured from patient records by the researchers using a newly developed set of 11 adherence criterias at a single time point
2. Perceived adherence by physicians to the perioperative pain management protocol measured using a newly developed questionnaire completed by physicians at a single time point

Key secondary outcome(s))
Patient characteristics measured using patient records at a single time point:
1. Age, sex
2. Body mass index (kg/m²)
3. Comorbidities
4. Date of amputation, indication for amputation, region and level of amputation
5. Preoperative pain management, perioperative pain management
6. Medication usage
7. American Society of Anesthesiologists Physical Status (ASA score)
8. Anaesthetic technique, surgical complications
9. Length of hospital stay
10. 30-day mortality

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Patients who underwent transfemoral amputation, knee disarticulation, transtibial- and (partial) foot amputations, and whose data were registered in EPIC
2. Interns and residents in vascular surgery, vascular surgeons, residents in anaesthesiology and anaesthesiologists involved in the amputation process

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
123

Key exclusion criteria
1. Patients younger than 18 years
2. Patients who underwent a toe amputation or a stump revision
3. Physician is no longer working in the hospital

Date of first enrolment
01/06/2017

Date of final enrolment
01/02/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Pain center
Location Beatrixoord Dilgtweg 5
Haren
Netherlands
9750 RA

Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request