

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/04/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Retrospective observational study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available (retrospective study)

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 measure

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

Secondary outcome measures

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

Overall study start date

10/12/2019

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

Age group

Adult

Sex

Both

Target number of participants

123

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

Sponsor details

Department of Anesthesiology, Pain Center

Location Beatrixoord

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Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/EN>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2022

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