Prevention of Phantom Limb Pain After Transtibial Amputation (PLATA) - Randomized, double-blind, controlled, multi-center trial comparing Optimized intravenous pain control vs Optimized intravenous pain control plus Regional anesthesia

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON41348

Source
ToetsingOnline

Brief title
PLATA

Condition

- Peripheral neuropathies

Synonym
Chronic pain, Phantom limb pain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Euroipean Society of Anaesthesiology (ESA)

Intervention

Keyword: phantom limb pain, prevention, regional anesthesia

Outcome measures

Primary outcome

Point prevalence of chronic phantom limb pain after 12 months.

Secondary outcome

- Subjective classification of chronic phantom limb pain by patient in the

preceding 4 weeks

- SF-12v2 Short form 12 quality of life assessment

- McGill short Pain Questionnaire

- Vascular preoperative status

- SIGAM mobility scale

- Inventarization of rehabilitation methods applied during follow-up

- Inventarization of drugs used to treat phantom limb pain

- Incidence of reamputation and surgical complications (bleeding, infection of

surgical site)

Study description

Background summary

Phantom limb pain following amputation is a major clinical problem. Current evidence how to best prevent phantom limb pain is equivocal because previous trials have included small numbers of patients, and tested heterogeneous patient collectives. There is some evidence that optimized perioperative pain control is effective in preventing phantom limb pain, but the potential added role of regional anesthesia has not been defined.

Study objective

The aim of this study is to test the hypothesis that a combination of optimized intravenous pain therapy and continuous sciatic nerve block decreases the point prevalence of phantom limb pain 12 months after transtibial amputation for peripheral vascular disease when compared to optimized intravenous pain therapy alone.

Study design

Interventional, randomized, prospective, triple-blind (patient, physician, statistician) clinical trial.

Intervention

Sciatic nerve block with continuous application of local anesthetic during surgery, and during the first week after surgery.

Study burden and risks

All patients, regardless of group allocation, will receive optimized intravenous pain treatment. The aim of this study is to assess whether additional regional anesthesia (ultrasound-guided sciatic nerve block) can further decrease the incidence of phantom limb pain.
The administration of both optimized intravenous pain treatment and peripheral nerve blockade is routine clinical practice for many procedures on the lower leg, including amputation. The risk of this intervention can be described as very low.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing elective transtibial amputation for peripheral vascular disease, age over 18 years, ASA* status II to IV.
* ASA American Society of Anesthesiology classification.

Exclusion criteria

- contraindication to peripheral regional anesthesia
- confirmed allergy to local anesthetics
- prior amputation resulting in current phantom limb pain
- severe psychiatric disease
- pregnancy or breastfeeding status
- amputation for tumour surgery
- traumatic amputation and
- inability to give written and informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2014
Enrollment:	130
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	bupivacaine
Generic name:	bupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2013
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-000875-33-NL
ClinicalTrials.gov	NCT01626755
CCMO	NL43843.018.13