

Intraneural Injection in local anesthetic blocks and nerve damage.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20134

Source

Nationaal Trial Register

Brief title

I4-study

Health condition

Any neurological deficit of the upper and lower extremities.

Sponsors and support

Primary sponsor: GJ Groen MD PhD; UMC Utrecht, Division of Perioperative Care & Emergency Medicine

Source(s) of monetary or material Support: UMC Utrecht, Division of Perioperative Care & Emergency Medicine;
Dutch Association for Regional Anesthesia

Intervention

Outcome measures

Primary outcome

Incidence of intraneural injection in electrical stimulation-guided nerve block with ultrasound visualisation.

Secondary outcome

To what extent intraneural injection leads to neurological sequelae at short-term and long-term follow-up.

Study description

Background summary

Rationale:

Unintentional injection of local anesthetics directly into a nerve (intraneurally) has long been recognized as a possible cause of nerve injury. However, recent studies have shown that ultrasound-guided brachial plexus penetration and intraneural injection does not inevitably cause neurological damage. Reliable data on the relative frequency of inadvertent intraneural injection during peripheral nerve blocks and to what extent these may lead to neural injury are lacking.

Study Objective:

To determine the incidence of intraneural injection in electrical stimulation-guided nerve block with ultrasound visualisation, and to what extent intraneural injection leads to neurological sequelae at short-term and long-term follow-up.

Study design:

This is a large, multi-centre cohort study in 805 adult patients undergoing upper or lower extremity local block. Patients and anesthesiologists are blinded for the ultrasound data. In addition, experts who analyse the ultrasound-acquired data are also blinded for patient's neurological status.

Eligibility:

Patients are eligible if they are undergoing upper or lower extremity block and are 16 years or older.

Study:

During peripheral nerve block, ultrasound data will be recorded just before, during and after injection. There will be no interference with the local standards of the procedure. The ultrasound data will then be analysed by two blinded, independent experts. All potential etiologic factors which are known to increase the risk of neurological damage are recorded (i.e., co-morbidities).

Follow-up:

The neurological status (motor and sensory) will be re-examined and recorded at their appearance for post-operative follow-up (3 days and 3 weeks), and after 3 months.

Primary outcome:

The occurrence of intraneural injections in electrical nerve stimulation-guided upper and lower extremity local anesthetic blocks as determined by ultrasound. Secondary outcome: the occurrence of patients with motor and/or sensory deficit at 3 days, 3 weeks and 3 months after the procedure. The results of both outcomes will be correlated for a possible relationship between intraneural injection and nerve damage.

Study objective

Intraneural injection of anesthetics in upper and lower extremity blocks increases the risk of neurological damage.

Study design

3 days post-op, 3 weeks and 3 months.

Intervention

Monitoring and recording the injection procedure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients scheduled for any surgery in the upper or lower extremity under electrical stimulation-guided local anesthetic block without prior (known) pre-existing;
2. neurological deficits in the upper or lower extremity.

Exclusion criteria

Age under 16 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2008
Enrollment:	805
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL1123
NTR-old	NTR1158
Other	UMC Utrecht, DP&S : I4
ISRCTN	Wordt niet aangevraagd/Observational study

Study results

Summary results

1. Moayeri N. Bigeleisen PE. Groen GJ. Quantitative architecture of the brachial plexus, surrounding compartments and their possible significance for plexus blocks. Anesthesiology 2008; in press;

2. Bigeleisen PE. Nerve puncture and apparent intraneural injection during ultrasound-guided

axillary block does not invariably result in neurologic injury. *Anesthesiology* 2006; 105:779-83