# Intraneural Injection in local anesthetic blocks and nerve damage.

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

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON20134

**Bron**
Nationaal Trial Register

**Verkorte titel**
I4-study

**Aandoening**

Any neurological deficit of the upper and lower extremities.

### Ondersteuning

**Primaire sponsor:** GJ Groen MD PhD; UMC Utrecht, Division of Perioperative Care & Emergency Medicine
**Overige ondersteuning:** UMC Utrecht, Division of Perioperative Care & Emergency Medicine;
Dutch Association for Regional Anesthesia

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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 than 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.

**Doel van het onderzoek**

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

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

Monitoring and recording the injection procedure.

# Contactpersonen

## Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age under 16 years.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Dubbelblind |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 08-01-2008 |
| Aantal proefpersonen: | 805 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1123 |
| NTR-old | NTR1158 |
| Ander register | UMC Utrecht, DP&S : I4 |
| ISRCTN | Wordt niet aangevraagd/Observational study |

# Resultaten

**Samenvatting resultaten**

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;<br>
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