

The Ehlers-Danlos syndrome and regional anesthesia.

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Locoregional anesthesia does not work as well in patients with the Ehlers-Danlos syndrome as in people who do not have this syndrome.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22447

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

The Ehlers-Danlos syndrome, locoregional anesthesia.

Het Ehlers-Danlos syndroom, cutis hyperelastica, locoregionale anesthesie

Ondersteuning

Primaire sponsor: sponsor: A.J.M. van Wijck, MD PhD, department of anesthesiology, UMC Utrecht

principal investigator: J.C. Mier, MD, department of anesthesiology, UMC Utrecht

Overige ondersteuning: Financial support will be organised by the Ehlers-Danlos patient association.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Analgesia in the region of the ulnar nerve within 60 minutes after application of an ulnar nerve block. This will be demonstrated by increasing stimuli from a neurostimulator. If the subject does not regard 20 mA as painful there is of an adequate block.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Ehlers-Danlos syndrome is a group of rare genetic disorders caused by a defect in collagen synthesis. Several patients from the Dutch Ehlers-Danlos patient organisation claimed that for them regional and local anaesthesia techniques did not work as good as would be expected. However, up to now there is no proof or explanation for this phenomenon. Hence this research project has started on request of the Ehlers Danlos patient organisation.

Ehlers-Danlos patients are to be expected to need frequent operations. The benefits and risks of regional in comparison with general anesthesia might be different in this group than in healthy people. With the results of this study it might become possible to make a more valid choice for the type of anaesthesia for the Ehlers-Danlos patients in the future.

Objective of the study:

Aim of this study is measuring the effects of locoregional anaesthesia in EDS patients and comparing these effects with those in a healthy control group. The results of this study can be used to make a more valid choice for the type of anaesthesia for the Ehlers-Danlos patients in the future.

Study design:

This study concerns a prospective case-control study of the effects of locoregional anaesthesia on Ehlers-Danlos patients versus a healthy control group

Study population:

25 people from 18 to 65 years old with all types of EDS except type IV, proven by a geneticist or person with comparable expertise.

25 controls, each matched with a person from the EDS-group for age and sex.

Intervention (if applicable):

1. An ulnar nerve block on the non dominant arm with 3 ml lidocaine 2%;
2. EMLA-cream, 1.5 gram applied on the dorsal side of the contralateral hand, covered with foil;
3. three times a field block of 3 by 3 cm by means of three subcutaneous injections on the dorsal side of the thorax. One will be five ml lidocaine 1%, one lidocaine 2% and one NaCl 0.9%.

Primary study parameters/outcome of the study:

Analgesia in the region of the ulnar nerve within 60 minutes after application of an ulnar nerve block. This will be demonstrated by stimuli from a neurostimulator above 20 mA which will not be regarded as painful in case of an adequate block.

Doel van het onderzoek

Locoregional anesthesia does not work as well in patients with the Ehlers-Danlos syndrome as in people who do not have this syndrome.

Onderzoeksopzet

The intervention and measurements will take two hours. After this time subjects can safely go home, there will be no further follow up.

Onderzoeksproduct en/of interventie

1. an ulnar nerve block on the non-dominant arm with 3 ml lidocaine 2%;
2. application of 1.5 gram EMLA-cream on the dorsal side of the contralateral hand, covered with foil;

3. three times a fieldblock of 3 by 3 cm by means of three subcutaneous injections on the dorsal side of the thorax; one with lidocaine 1%, one lidocaine 2% and one with NaCl 0.9%.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

For the Ehlers-Danlos group:

1. people with all types of Ehlers-Danlos except type IV, proven by a geneticist or a comparably qualified person;
2. 18 to 65 years old;
3. informed consent.

For the control group:

All subjects are matched with a patient from the Ehlers-Danlos group for age and sex.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For Ehlers-Danlos patients:

1. Type IV Ehlers-Danlos;
2. co-existing disease which increases the risk of locoregional anesthesia, according to prudent daily clinical practice;
3. hereditary acquired or drug induced bleeding disorders;
4. periferale mononeuropathy, polyneuropathy, multiple sclerosis or other relevant neurologic disorder.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31537

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1064
NTR-old	NTR1097
CCMO	NL13893.041.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31537

Resultaten

Samenvatting resultaten

N/A