The Ehlers-Danlos syndrome and regional anesthesia.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22447

Source
Nationaal Trial Register

Brief title
N/A

Health condition

The Ehlers-Danlos syndrome, locoregional anesthesia.

Het Ehlers-Danlos syndroom, cutis hyperelastica, locoregionale anesthesie

Sponsors and support

Primary 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
Source(s) of monetary or material Support: Financial support will be organised by the Ehlers-Danlos patient association.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Analgesia from the subcutanous injections and the topical application of EMLA cream. Time of onset of analgesia. Time of end of analgesia. Duration of analgesia.

Study description

Background summary

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 anaestesia on Ehlers-Danlos patients versus a healthy control group

Study population:

25 people from 18 to 65 years old with al 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 applicated 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 subcutanous injections on the dorsal side of the thorax. One will be five ml lidocaine 1%, one lidocaine 2% en 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.

Study objective

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

Study design

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

Intervention

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%.

Contacts

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Eligibility criteria

Inclusion criteria

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 sexe.

Exclusion criteria

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. periferal mononeuropathy, polyneuropathy, multiple sclerosis or other relevant neurologic disorder.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 31537
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A