The Ehlers-Danlos syndrome and regional anesthesia

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON31537

Source
ToetsingOnline

Brief title
The Ehlers-Danlos syndrome and regional anesthesia

Condition

- Musculoskeletal and connective tissue disorders congenital
- Connective tissue disorders (excl congenital)
- Epidermal and dermal conditions

Synonym
Ehlers-Danlos syndrome, mesenchymose

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,aanvraag in voorbereiding,wetenschappelijk fonds EDS-patientenvereniging

Intervention

Keyword: anesthesia, Ehlers-Danlos, nerve block, regional

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 stimuli from a neurostimulator above 20 mA which will not be regarded as painful in case 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

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.

Study objective

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

Intervention

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%.

Study burden and risks

Burden:
Completing a questionnaire at home, amplified with a physical examination in hospital on the day of the measurements to evaluate the risks of regional anaesthesia for the subject.
Application of EMLA-cream on the back of the hand, followed by an ulnar nerve block, performed as in clinical practice.
Finally three subcutanous injections on the on the dorsal side of the thorax are administered.

Risks
1) In high dose local anaesthetics can give intoxication. The administered dose of lidocain in this study is far below this toxic dose (pg 14 protocol). If nevertheless symptoms of intoxication do occur, all equipment, medication, nurses and staff are present to treat this immediately. For this reason all injections will take place in the OR, after which monitoring will be continued in the recovery room
2) Every injection can cause a haematoma.
3) The onset and duration of the analgesic effects are averages from literature. Analgesia can be longer than expected but will always be temporary.
4) There is a theoretical risk of ulnar neuropathy after an ulnar block. In

literature there is no case report of ulnar neuropathy after an ulnar block with lidocaine; the occurrence is extremely unlikely.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

For EDS patients
- People with all types of the Ehlers-Danlos Syndrome except type IV (the vascular type), proven by a geneticist or a comparably qualified person
- 18 to 65 years old
- Infomed consent;For the control group
- All subjects are matched with a patient from the EDS group for age and sex

Exclusion criteria

For EDS patients
- EDS type IV (vascular type)
- No informed consent
- Younger than 18 or older than 65 years old
- Co-existing disease which increases the risk for regional anesthesia, this according to prudent daily clinical practice in the OR
- Hereditary or acquired (including drug induced) bleeding disorders
- Periferal mononeuropathy, polyneuropathy, Multiple Sclerosis or other relevant neurologic disorders;Control group
- EDS or direct family with EDS because of the possibility of undiagnosed EDS in the subject
- No informed consent
- Younger than 18 or older than 65 years old
- Co-existing disease which increases the risk for regional anesthesia, this according to prudent daily clinical practice in the OR
- Hereditary or acquired (including drug induced) bleeding disorders
- Periferal mononeuropathy, polyneuropathy, Multiple Sclerosis or other relevant neurologic disorders

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2009
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	EMLA cream
Generic name:	lidocaine/ prilocaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	lidocaine 1%
Generic name:	lidocaine 1%
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	lidocaine 2%
Generic name:	lidocaine 2%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22447
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2006-004656-20-NL
CCMO	NL13893.041.07
Other	volgt
OMON	NL-OMON22447