Autofluorescent flavoprotein imaging of intraepidermal nerve fibers: a pilot study

Published: 18-08-2014
Last updated: 21-04-2024

To study whether flavoprotein imaging can be used to diagnose painful polyneuropathy, we first need to investigate whether a reproducible and validated flavoprotein signal can be obtained on the second fingertip of healthy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON44279

Source
ToetsingOnline

Brief title
Imaging pain

Condition

- Peripheral neuropathies

Synonym
nerve pain, neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Erasmus MC Pijnfonds

Intervention

Keyword: Epidermal, Flavoprotein, Imaging, Nerve

Outcome measures

Primary outcome

-size and time course of the flavoprotein response

-linearity of the electrical stimulation with the flavoprotein response

-blockade of the flavoprotein response by lidocaine/prilocaine cream and

capsaicin 8% patches

Secondary outcome

not applicable

Study description

Background summary

Painful polyneuropathy is a common condition that is difficult to diagnose and to treat and which has a negative impact on quality of life. Painful polyneuropathy, is caused by degeneration of small nerve fibers. With current techniques, the diagnosis of small fiber neuropathy is not set reliably. Flavoprotein is an optical method suitable to reliably measure activation by nerve nerve fiber endings in the spinal cord. Because the epidermis also contains a high density of (small) nerve fiber endings, we hypothesize that flavoprotein imaging is suitable for diagnosing small fiber neuropathy.

Study objective

To study whether flavoprotein imaging can be used to diagnose painful polyneuropathy, we first need to investigate whether a reproducible and validated flavoprotein signal can be obtained on the second fingertip of healthy subjects.

Study design

-to examine whether there is a temporal relationship between administration of an electrical stimulus by means of finger electrodes, and an optical

(flavoprotein) signal on the fingertip of subjects
-to examine whether there is a linear relationship between the strength of the applied electrical signal, and the size of the optical (flavoprotein) signal
-to study whether the signal is specific for the flavoprotein wavelength, by means of the exchange of the filter settings of the camera
-to study whether the optical (flavoprotein) signal can be blocked by means of administration of lidocaine / prilocaine cream on the fingertip
-to study whether the optical (flavoprotein) signal can be blocked by means of administration of a capsaicin 8% patch to the fingertip

Intervention

intervention with lidocaine / prilocaine cream and capsaicin 8% patches is not the purpose of the study, but serves as a negative control.

Study burden and risks

-time: 45 minutes per person
-discomfort: brief painful electrical stimulation, approximately 3 hour numbness of the index fingertip, about 3 days hypersensitivity to pressure and temperature of the middle fingertip
-risk: no

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

healthy volunteers

Exclusion criteria

-younger than 18 years
-pre-existing neuropathy
-previous allergic reaction to local anaesthetics

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	EMLA cream
Generic name:	lidocaine/prilocaine cream 25mg/g
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Qutenza patch
Generic name:	capsaicine 8% patch
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-08-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2014-002561-29-NL
CCMO	NL49568.078.14