Applicability of cornea confocal microscopy in the diagnosis of small fiber neuropathy.

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We purpose to determine whether the international normative values are applicable in our center in 10 healthy participants. Furthermore, CCM will be introduced as additional diagnostic tool in patients with (possible) SFN.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON42708

Source
ToetsingOnline

Brief title
Cornea confocal microscopy in small fiber neuropathy.

Condition

- Peripheral neuropathies

Synonym
small fiber neuropathie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cornea confocal microscopy, diagnostics, small fiber neuropathy

Outcome measures

Primary outcome

Corneal nerve fiber density (CNFD), branch density (CNBD), fiber length (CNFL),

and the tortuosity coefficient (CNFT) will be determined in all participants.

Secondary outcome

-

Study description

Background summary

According the international criteria, the diagnosis small fiber neuropathy (SFN) is based on clinical symptoms in combination with a reduced intraepidermal nerve fiber density (IENFD) in skin biopsy and/or abnormal temperature threshold testing (TTT). The sensitivity of skin biopsy is moderate to good, although IENFD is normal in about 12% of patients with SFN complaints. Furthermore, TTT is a widely available diagnostic tool, but this test lacks specificity. Corneal confocal microscopy (CCM) had been described and is used in clinical practice as an objective, non-invasive diagnostic tool to detect small nerve fiber damage in patients with diabetes mellitus. This study examines the applicability of CCM in patients with possible SFN, and the value of CCM as an additional diagnostic tool in SFN.

Study objective

We purpose to determine whether the international normative values are applicable in our center in 10 healthy participants. Furthermore, CCM will be introduced as additional diagnostic tool in patients with (possible) SFN.

Study design

The study has a cross-sectional design.

Study burden and risks

The ophthalmologic examination has no special hazard for the condition of the participants.
There is a very small risk of corneal erosion. This is a superficial wound of the cornea. After the examination, normal vision is expected. It is not recommended to wear contact lenses on the research day, both before and after the examination.
In total, completing the questionnaire and the entire ophthalmological examination cost about 25 minutes.

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 subjects (n<=20)
a. Male and female subjects of 18 years or older

b. One or less positive answers on the SFN-SIQ
c. Written informed consent;Patients (n<=200):
Those who are referred to our center for the analysis of possible small fiber neuropathy are eligible for participation in this study.

Exclusion criteria

Healthy subjects (n=20)
- Sensory symptoms in hands or feet or known with mono-/polyneuropathy.
- Known illnesses that can cause neuropathy, like diabetes mellitus, renal failure, alcohol abuse, rheumatoid arthritis, SLE, sarcoidosis, and thyroid dysfunction.
- History of diseases of the eye such as dry eyes, atopic keratoconjunctivitis, epithelial membrane basement dystrophies, cystic corneal disorders, which all affect corneal innervation.
- Patients with chronic glycemic exposure since this is a strong risk factor for corneal subbasal nerve loss.
- Use of medication (also in the past) known to possibly cause polyneuropathy.;Patients (n=200)
- History of diseases of the eye (such as mentioned above);Participants are excluded from this study when they do not want to be informed about defects or accidental findings which could be found during the pre-screening of the ophthalmologist.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2016
Enrollment:	220

Type:	Actual

Ethics review

Approved WMO Date:	12-10-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL53973.068.15

Study results

Date completed:	22-06-2017
Actual enrolment:	225