Assessment of the microvascular architecture of the lip and nailfold by orthogonal polarisation spectrum imaging

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To assess the microvascular architecture in lip and nailfold of healthy volunteers. To determine reproducibility of the OPS imaging technique for assessment of microvascular architecture.

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON31292

Source
ToetsingOnline

Brief title
Microvascular architecture by OPS imaging

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Microvascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Nierziekten

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Imaging, microvasculature, OPS, Vascular function

Outcome measures

Primary outcome

Microvascular architecture of the lip and nail fold.

Secondary outcome

None

Study description

Background summary

In subjects with hypertension and diabetes the microvasculature plays an important role in the pathogenesis of the technique. Although several techniques are available for assessment of macrovascular structure and function, few and inferior techniques are used foor assessing microvascular structure. A new technique, orthogonal polarisation spectrum imaging is a promising new method to perform microvascular structure measurements.

Study objective

To assess the microvascular architecture in lip and nailfold of healthy volunteers. To determine reproducibility of the OPS imaging technique for assessment of microvascular architecture.

Study design

Observational in healthy volunteers.

Four measurements are performed in each lip quadrant (2 upper lip and 2 lower lip quadrants). Thus a total of 16 measurements. Each subject is measured on 2 occasions. Nailfold microvascular architecture is determined before and after a 2-minute inflation of a finger cuff.

Study burden and risks

Very limited time burden. No relevant risk due to non-invasive character of the measurements.

Contacts

Public
Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-70 years

Exclusion criteria

• Smoking (within 1 year prior to screening)
• History of cardiovascular disease

• History of malignancy
• Use of any investigational agent in the last 30 days
• History of chronic inflammatory disease
• History of chronic skin diseases
• History of diabetes mellitus
• History of alcohol or drug abuse within the last 5 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL17602.058.07