Pilot study to asses the dependence of skin autofluorescence (SAF) on skin color and skin tissue characteristics in humans with dark skin

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Assess feasibility of development of skin colour independent assessment of skin AGE accumulation by measurement of skin autofluorescence in persons with dark skin

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43312

Source
ToetsingOnline

Brief title
Pilot study skin autofluorescence (SAF) in dark skin

Condition

- Other condition
- Pigmentation disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
not applicable

Health condition

afhankleijkheid meting van huidskleur

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Diagnoptics Technologies,IAG4 subsidieProvinciale Staten Groningen

Intervention

Keyword: fluorescence, skin colour

Outcome measures

Primary outcome

The following measurements, and two 3 mm punch skin biopsies will be performed

on the volar sitd of one of the forearms approximately 10 cm

below the elbow fold:

- In vivo skin autofluorescence and reflection measurements, with the

conventional research version of the AGE readers ((which includes a

high-quality spectrometer)

- Measurement of skin colour and type using non-invasive Mexameter.

- In vivo skin diffuse optical spectroscopy for the assessment of optical

properties of the skin measurements will be made by a

non-invasive instrument of Quaspec.

- Standard biochemical assay of one of the conventional 3-mm skin biopsies for

the assessment of concentrations of the following advanced

glycation endproducts, pentosidine, CML and MGH-1 with use of UPLC and tandem

mass spectroscopy

- light microscopy of the other skin punch biopsy. In transversal coupes autofluorescence measurements will be performed with a set of different excitation wavelengths, including 370 nm, similar to that of the AGE reader. Next, in contiguous slices of this skin biopsy, imaging will be performed using AGE antibodies to assess the spatial distribution of autofluorescence and of specific advanced glycation endproducts. Candidates for the antibody AGE dose against pentosidine, CML and MGH-1. This part of the studies will be performed in corporation with the Department of Dermatology UMCG and the UMIC UMCG.

Secondary outcome

n.a.

Study description

Background summary

Skin autofluorescence measurements are increasingly used to estimate cardiovascular risk. Skin autofluorescence is assumed to give an estimate of the accumulation of advanced gl.ycation endproducts (AGE) in the dermis of the skin, and with that, in other tissues of the body with slow turnover such as the vessel wall and the myocardium.
This accumulation of AGE deteriorates vessel function and structure.
Skin autofluorescence has been shown to be an independent predictor of cardiovascular events. This has been supported by earlier studies of our group and others using skin biopsies, and with skin autofluorescence measurements, in clinical follow-up studies, which were performed in the large majority in Caucasian and North-Asian healthy persons and in people with diabetes, renal failure or pre-existing cardiovascular disease.
For persons with the darker skin types such as persons from sub-Saharan Africa and South Asia (Tamil Nadu) support is lacking for the relation between measured skin autofluorescence and AGE accumulation.
In the present pilot proposal a set of skin measurements is performed, which should make it clear whether further development of a skin colour-independent

assessment of AGEs is feasible

Study objective

Assess feasibility of development of skin colour independent assessment of skin AGE accumulation by measurement of skin autofluorescence in persons with dark skin

Study design

The current pilot proposal concerns the following parts:
- experimental part with skin measurements and skin biopsies in persons with dark skin colour
- assessment of feasibility to develop model based translation of measured skin fluorescence into AGE accumulation, independent of skin colour and skin type

The following measurements, and a two 3 mm punch skin biopsies will be performed on the volar side of one of the forearms approximately 10 cm below the elbow fold.
- In vivo skin autofluorescence and reflection measurements, with the conventional research version (which includes a high-quality spectrometer) of the AGE reader
- Measurement of skin colour and type using non-invasive Mexameter.
- In vivo skin diffuse optical spectroscopy for the assessment of optical properties of the skin measurements will be made by a non-invasive instrument of Quaspec.
- Standard biochemical assay of one of two conventional 3 mm skin biopsies for the assessment of concentrations of the following advanced glycation endproducts, pentosidine, CML and MGH-1 with use of UPLC and tandem mass spectroscopy
- light microscopy of the other 3 mm skin biopsy. In transversal coupes autofluorescence measurements will be performed with a set of different excitation wavelengths, including 370 nm, similar to that of the AGE reader.
Also, in contiguous slices of the skin biopsy, imaging will be performed using AGE antibodies to assess the spatial distribution of autofluorescence and of specific advanced glycation endproducts.

Study burden and risks

The participants will make one study visit to the UMCG.

The main burden is two conventional 3 mm punch skin biopsies from the inner side of the lowerarm 10 cm below the elbow fold, after local anesthesia. In case of persistent bleeding a suture will be placed. The risk

associated with this biopsy is local bleeding or infection,
this risk is low (both < 1%).

All other (preceding) measurements (with AGE readers, Mexameter, Quaspec) are noninvasve, not painful, en without risk, the measurements will
take appr. 30 minutes overall.

The participants will have no direct benefit.

Group relatedness not applicable

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

6 healthy persons and 6 patients with diabetes with a wide age range, all with a dark (Fitzpatrick class IV-VI) skin colour

Exclusion criteria

skin disease ot other local skin abnormalities (such as scars or tattoos)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2016
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	AGE reader
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	26-09-2016
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL57906.042.16