Can skin autofluorescence become a risk indicator for retinal detachment ?

Published: 18-10-2011
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The aim of this study is to investigate whether the risk and severityof retinal detachment are related to skin autofluorescence (AF).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON35809

Source
ToetsingOnline

Brief title
Can skin autofluorescence become a risk indicator for retinal detachment ?

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal ablation or detachment

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: advanced glycation, retina, skin autofluorescence

Outcome measures

Primary outcome

Primary endpoint: the relation between skin AF,vitreous body AGE levels, and

plasma AGE levels.

Secondary outcome

Secondary endpoint: relation between vitreous body AGE levels and severity of

retinal detachment.

Other study parameters: verbally asked questions about cardiovascular history,

concomitant disease and medication, and current and previous smoking habits

Study description

Background summary

With aging, structural changes develop in the vitreous body. This can be followed by the development of a posterior vitreous detachment, which can induce retinal damage such as intravitreal hemorrhage, retinal tear and retinal detachment.
The importance of collagen fibrils in maintaining the vitreous gel structure leads to the logical assumption that changes in the gel structure could be directly related to changes in the collagen fibrils. These changes can be caused by forming advanced glycation endproducts (AGEs), which involves a series of non-enzymatic reactions with reducing sugars, oxoaldehydes, oxidized lipids and reactive carbonyls. AGEs form arbitrarily on any protein, dependent on the concentration of reactive molecules, and, once settled, they can only be removed by degradation of the protein.
Recently, it has been suggested that AGEs may be involved in vitreo-retinal interface diseases. . It would be clinically interesting to find out whether AGE content in the vitreous body is a predictor of risk of retinal detachment. However, only invasive techniques for assessing AGE content of the vitreous body are available. This is not appropriate to function as a predictor. Plasma or serum AGE assays may be used, but these are often not representative for the actual accumulation of AGE in tissue.
A possible solution is the use of skin autofluorescence, measured by an AGE reader. The AGE reader has been validated on skin biopsy levels of pentosidine, carboxymethyllysine (CML) and carboxyethyllysine (CEL) in several patient

groups and healthy persons. Skin autofluorescence might also correlate with AGE accumulation in the vitreous body.

Study objective

The aim of this study is to investigate whether the risk and severityof retinal detachment are related to skin autofluorescence (AF).

Study design

The study will potentialy consist of three phases:
1. First, in a pilot study the presumed relation between skin AF and vitreous body AGE levels will be tested in post-vitrectomy patients with known levels of AGEs in the vitreous body. Skin AF and blood sampling will be performed in patients.
2. Second, if the relation of skin AF to vitreous body AGE levels is confirmed in the pilot study, this relation will be tested cross-sectionally in patients who undergo vitrectomy because of retinal detachment

Optionally 3. Third, if there is some evidence found to assume that skin AF is an early predictor of the risk and severity of retinal detachment, we intend to write a subsequent protocol to investigate this further in a follow-up study. This part is not yet included in the present METC submission.

Study burden and risks

none, except those of single i.v. blood drawing

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

• Willingness to participate.
• (Post-) vitrectomy patients, previously diagnosed with retinal detachment.
• Age: >18 years.

Exclusion criteria

• Unwillingness to participate.
• Dark coloured skin (Fitzpatrick type V or VI).
• Skin abnormalities on both arms that will impair the reliability of the autofluorescence measurement.
• Local or general active infection or inflammatory disease.
• Known renal disease, current dialysis treatment, or a history of renal transplantation.;Exclusion criteria only for the pilot study
• Known diabetes mellitus.
• Pre-existing cardio-vascular complications
• Intra-ocular implant lens.

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):	11-11-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2011
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	NL37322.042.11