

The role of skin autofluorescence as a predictor for post-operative proliferative vitreoretinopathy and surgical failure in patients with retinal detachment

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The aim of this study is to investigate whether skin autofluorescence (AF) is predictive of postoperative PVR (and corresponding surgical failure) in patients being surgically treated for retinal detachment and to investigate some pathways which may...

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-OMON38541

Source

ToetsingOnline

Brief title

Skin autofluorescence and surgical failure in retinal detachment patients

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym

(rhegmatogenous) retinal detachment

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: advanced glycation, retina, skin autofluorescence

Outcome measures

Primary outcome

- The relation between skin AF and failure of surgery for retinal detachment
- The relations between skin AF and PVR (pre- and postoperative), vitreous body

AGE and sRAGE levels, plasma sRAGE levels and glyoxalase and RAGE polymorphisms.

Secondary outcome

Relation between surgical failure and clinical risk factors for post-operative PVR.

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. Although these eye conditions remain without (serious) symptoms in the majority of subjects, they are insidious and can lead to permanent visual loss and blindness. It is difficult to identify high risk

subjects based on eye examination. Therefore, in order to identify those subjects at increased risk for severe disease progression, it is of importance to gain more insight into the relation between general ageing and age-related disease in the eye.

It was found that skin autofluorescence (skin AF) was independently associated with the severity of retinal detachment (degree of retinal detachment and presence of proliferative vitreoretinopathy (PVR)) at the time of surgery.

Since it has been shown that preoperative PVR is the best clinical predictor of postoperative PVR and hence surgical failure, skin autofluorescence might also predict postoperative PVR.

Study objective

The aim of this study is to investigate whether skin autofluorescence (AF) is predictive of postoperative PVR (and corresponding surgical failure) in patients being surgically treated for retinal detachment and to investigate some pathways which may contribute to the explanation of the relation of systemic skin AF with local eye disease.

Study design

The objectives will be tested in a prospective cohort study in patients who will undergo vitrectomy because of retinal detachment.

Study burden and risks

The participants will have the burden of a single skin AF measurement, and a single venipuncture, and will be approached for clinical follow-up assessment;. Future general benefit may be that a more focused and accurate, rapid non-invasive and low-cost prediction of risk of proliferative vitreoretinopathy and/or surgical failure in retinal detachment patients will become available.

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.
- Patients, diagnosed with retinal detachment, scheduled for vitrectomy.
- Age: >18 years.

Exclusion criteria

- 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 with impairment of renal function class CKD ≥ 3 (≤ 60 ml/min according to eGFR), current dialysis treatment, or a history of renal transplantation.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 11-11-2013
Enrollment: 500
Type: Actual

Ethics review

Approved WMO
Date: 07-08-2013
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 13-11-2013
Application type: Amendment
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	NL43547.042.13