Skin autofluorescence and surgical failure in retinal detachment patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27827

Source
NTR

Brief title
-

Health condition

Rhegmatogenous retinal detachment (RRD) is a sight-threatening condition, most often initiated by a posterior vitreous detachment-associated retinal tear. A recent study found an incidence of RRD in the Netherlands of 18.2 per 100,000 people.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

1. Surgical failure

Secondary outcome

2. Skin autofluorescence

3. Vitreous body AGE levels

4. Vitreous body sRAGE levels

5. plasma sRAGE levels

6. Glyoxalase polymorphisms

7. RAGE polymorphisms

8. Age,

9. gender,

10. surface area of retinal detachment,

11. number of retinal defects,

12. macular detachment,

13. detachment duration,

14. pre-operative PVR grade,

15. presence of diabetes,

16. pseudophakia,

17. intraoperative use of gas or silicon oil,

18. intraoperative cryotherapy, intraoperative minor hemorrhage.

Study description

Background summary

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

Study objective

Advanced glycation endproducts (AGEs) may play a role in the development of PVR and hence surgical failure. Possibly, autofluorescence of AGEs in the skin, measured by the simple non-invasive AGE reader, could be used as a predictor for post-operative proliferative vitreoretinopathy and surgical failure in patients with retinal detachment.

Study design

1. Surgical failure - Re-detachment - Timepoint: 3 months

2. Skin autofluorescence - AGE reader MU - Timepoint: 0

Vitreous biopsy - timepoint: 0 - 14 days
3. Vitreous body AGE levels - high performance liquid chromatography (HPLC)- Timepoint: After inclusion of all patients.

4. Vitreous body sRAGE levels - Enzyme linked immunosorbent (ELISA) techniques - Timepoint: After inclusion of all patients.

5. plasma sRAGE levels - Enzyme linked immunosorbent (ELISA) techniques - Timepoint: After inclusion of all patients.

6. Glyoxalase polymorphisms - Genotyping techniques - Timepoint: After inclusion of all patients.

7. RAGE polymorphisms - Genotyping techniques - Timepoint: After inclusion of all patients.

8. Age - Timepoint:0

9. gender - Timepoint:0

10. surface area of retinal detachment - Timepoint: Vitreous biopsy

11. number of retinal defects - Timepoint: Vitreous biopsy

12. macular detachment - Timepoint: Vitreous biopsy

13. detachment duration - Timepoint: Vitreous biopsy

14. pre-operative PVR grade - Timepoint: Vitreous biopsy

15. presence of diabetes - Timepoint:0

16. pseudophakia - Timepoint: 0

17. intraoperative use of gas or silicon oil - Timepoint: Vitreous biopsy

18. intraoperative cryotherapy, intraoperative minor hemorrhage - Timepoint: Vitreous biopsy

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

1. Willingness to participate.

2. Patients, newly diagnosed with retinal detachment, scheduled for vitrectomy.

3. Age: >18 years.

Exclusion criteria

1. Dark coloured skin that impairs the reliability of the autofluorescence measurement.

2. Skin abnormalities on both arms that will impair the reliability of the autofluorescence measurement.

3. Local or general active infection or inflammatory disease.

4. 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 non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	27-11-2013
Application type:	First submission

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
NTR-new	NL4145
NTR-old	NTR4289
Other	METc UMCG : METc 2013/153
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A