Evaluation of the relationship between AGEs and treatment outcome of vitrectomy in PDR patients

No registrations found.

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

Summary

ID

NL-OMON22139

Source
NTR

Brief title
TBA

Health condition

diabetes mellitus, diabetic retinopathy

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

the relation between skin AF and visual outcome of PDR patients at 1 year after vitrectomy.

Secondary outcome

re-vitrectomy rate within the first year.

Study description

Background summary

Rationale
Proliferative diabetic retinopathy (PDR) is one of the major causes of blindness in diabetic patients. Currently, the main treatment options of PDR are panretinal laser coagulation and vitrectomy surgery. However, the treatment outcome is unsatisfactory. Although a majority of patients have improved visual acuity after surgery, they cannot regain sufficient vision for daily life.
Advanced glycation endproducts (AGEs) are protein bound compounds derived from glycemic and oxidative stress with fluorescent properties. AGEs are thought to play an important role in the pathogenesis of DR by binding to the receptor for AGEs, which leads to endothelial dysfunction, microglia activation, breakdown of the blood-retinal barrier, and upregulation of toxic cytokines. AGEs can be assessed non-invasively with skin autofluorescence (SAF), which make it a potential biomarker for diabetic screening. SAF and AGEs were reported to be correlated with the chance of developing type 2 diabetes mellitus, and AGEs with the severity of DR, and to have better predictive ability than hemoglobin A1c.

Objective
The aim of this study is to investigate the relationship between AGEs and treatment outcome to vitrectomy in PDR patients.

Study design
This study is a cross-sectional cohort study.

Study population
In this study, patients who have been diagnosed with PDR and have been or will be treated according to current guidelines with vitrectomy in the department of ophthalmology at the UMCG will be investigated

Intervention (if applicable)
Pars plana vitrectomy, with or without cataract extraction, with or without pre-operative laser treatment or anti-VEGF injection

Main study parameters/endpoints
Primary endpoint: the relation between skin AF and visual outcome of PDR patients at 1 year after vitrectomy.
Secondary endpoint: re-vitrectomy rate within the first year.

Study objective

skin autofluorescence is a predictor of treatment responsiveness in patients who underwent

vitrectomy because of PDR

Study design

baseline, 1 year

Intervention

skin autofluorescence measurement (non invasive)

Contacts

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Eligibility criteria

Inclusion criteria

• Willingness to participate.
• Age: >18 years.
• Patients diagnosed with PDR who have undergone or will undergo vitrectomy at the UMCG.
• Patients who have at least 1-year follow-up with BCVA after vitrectomy at the UMCG will be included.

Exclusion criteria

• Unwillingness to participate.
• Dark coloured skin (Fitzpatrick type V or VI), which will impair the reliability of the autofluorescence measurement.
• 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.
• Patients with high myopia (>6 diopters), glaucoma, combined retinal disease, prior vitreoretinal surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-08-2020
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-07-2020
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	NL8793
Other	METC UMCG : METC 2020/350

Study results