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

Gepubliceerd: 23-07-2020 Laatst bijgewerkt: 07-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22139

Bron
NTR

Verkorte titel
TBA

Aandoening

diabetes mellitus, diabetic retinopathy

Ondersteuning

Primaire sponsor: University of Groningen
Overige ondersteuning: University of Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

baseline, 1 year

Onderzoeksproduct en/of interventie

skin autofluorescence measurement (non invasive)

Contactpersonen

Publiek

University Medical Center Groningen
L.I. Los

050-3612510

Wetenschappelijk

University Medical Center Groningen
L.I. Los

050-3612510

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	28-08-2020
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8793
Ander register	METC UMCG : METC 2020/350

Resultaten