

# Evaluation of the responsiveness of anti-VEGF treatment in DME

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON29053

### Source

NTR

### Brief title

HRDDME

### Health condition

diabetic retinopathy (DR)

## Sponsors and support

**Primary sponsor:** GSMS

**Source(s) of monetary or material Support:** GSMS

## Intervention

## Outcome measures

### Primary outcome

treatment success

### Secondary outcome

1 year BCVA and macular thickness

## Study description

### Background summary

We aim to evaluate hyperreflective dots (HRDs) on optical coherence tomography (OCT) in patients with diabetic macular edema (DME) to assess their relationship with the treatment outcomes.

### Study objective

The number of pretreatment HRDs on OCT can predict response to intravitreal anti-VEGF therapy in DME.

### Study design

baseline, 1 year

### Intervention

none

## Contacts

### Public

University Medical Center Groningen  
L.I. Los

050-3612510

### Scientific

University Medical Center Groningen  
L.I. Los

050-3612510

## Eligibility criteria

### Inclusion criteria

DME patients with completion of 6 intravitreal injections of anti-VEGF at UMCG and at least 1

year follow-up with BCVA  
and OCT after start of the treatment will be included.

## Exclusion criteria

high myopia (>6 diopters), glaucoma, media opacities interfering with OCT imaging, combined retinal disease, intraocular surgery within 12 weeks prior to the first injection, vitreomacular traction on SD-OCT and those whose SD-OCT images were of poor quality

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	26-02-2020
Enrollment:	70
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	26-02-2020
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	NL8392
Other	METC UMCG : METc2019/599

## Study results