# DIABETIC RETINOPATHY: THE ROLE OF LIPOPROTEIN(A)

Published: 22-10-2018
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To demonstrate whether a statistically significant difference exists between T2D patients with and without DR.

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|---|---|
| **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-OMON46153

**Source**
ToetsingOnline

**Brief title**
DR & Lp(a)

### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

**Synonym**
diabetic retinopathy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam
**Source(s) of monetary or material Support:** Rotterdamse Stichting Blindenbelangen;Oogfonds & Landelijke Stichting voor Blinden en Slechtzienden

## Intervention

**Keyword:** Diabetic retinopathy, Lp(a)

## Outcome measures

### Primary outcome

Lp(a) concentration.

### Secondary outcome

Molecular characteristics Lp(a).

# Study description

### Background summary

Diabetic retinopathy (DR), a microvascular complication of type 2 diabetes (T2D), may lead to local ischemia and inflammatory reactions and, ulimately, to irreversible vision loss. A high Lp(a) concentration comprises a risk factor for developing cardiovascular disorders in general and, apparently also, for DR. It is conjectured that T2D patients with DR have an increased Lp(a) concentration (associated with a reduced number of Kringle IV repeats).

### Study objective

To demonstrate whether a statistically significant difference exists between T2D patients with and without DR.

### Study design

Comparative, non-randomised, observational.

### Study burden and risks

Participants do not benefit, risks are negligible, burden is low.

# Contacts

### Public

Oogziekenhuis Rotterdam

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Age >= 18 years
Informed consent
Diabetic retinopathy

## Exclusion criteria

Other retinal pathology
Glaucoma

# Study design

### Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-12-2018 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 22-10-2018 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 | NL66405.078.18 |