

# Peripheral laserphotocoagulation in patients with bilateral drusen

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
20/12/2005	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/12/2005	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
05/11/2008	Eye Diseases	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

OZR-2002-15; NTR192

## Study information

### Scientific Title

### Study objectives

Peripheral laserphotocoagulation reduces drusen area in patients with bilateral drusen.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Received from the local medical ethics committee

**Study design**

Multicentre, randomised, active controlled, parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Bilateral drusen

**Interventions**

Laser photocoagulation peripheral retina.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Total drusen area
2. Vision (ETDRS)

**Key secondary outcome(s))**

No secondary outcome measures

**Completion date**

01/04/2005

## **Eligibility**

**Key inclusion criteria**

1. Greater than or equal to 10 drusen (greater than 63 µm) within a 3 mm radius from the fovea
2. Vision less than 0.5
3. No new or previous neovascularisation
4. No sub-retinal pigment epithelium (sub-RPE) serous fluid greater than 1 MPS disc area
5. No geographical atrophy within a radius of 500 µm of the fovea
6. If myopic: less than 8 diopters
7. No previous retinal laser treatment
8. No serious proliferative or non-proliferative diabetic retinopathy of diabetic macula oedema

9. No progressive eye disease
10. Aged greater than or equal to 50 years
11. Bilateral fundus photograph and fluorescein angiography (FAG) of the eye to be treated (less than 2 weeks before treatment)
12. Ability and willingness to participate in 2 year follow-up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Additional laser treatment during follow-up period
2. Vitreous or retina intervention during follow-up
3. Inspection of one of both eye is no longer possible

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

01/04/2005

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Oogziekenhuis Rotterdam

Rotterdam

Netherlands

3011 BH

## Sponsor information

**Organisation**

Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

**ROR**

<https://ror.org/02hjc7j46>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Foundation of Scientific Research at the Eye Hospital (Stichting Wetenschappelijk Onderzoek het Oogziekenhuis) (The Netherlands)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration