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# Peripheral laserphotocoagulation in patients with bilateral drusen

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|---|---|---|
| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>05/11/2008 | **Condition category**<br>Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Bilateral drusen

### Interventions
Laser photocoagulation peripheral retina.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
1. Total drusen area
2. Vision (ETDRS)

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/01/2003

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
16

### 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**
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# Sponsor information

**Organisation**
Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

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**Sponsor type**
Hospital/treatment centre

**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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration