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Peripheral laserphotocoagulation in patients with bilateral drusen

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 05/11/2008	**Condition category** 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
Rotterdam
Netherlands
3011 BH

Sponsor information

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

Sponsor details
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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