

Peripheral laserphotocoagulation in patients with bilateral drusen

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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