

Randomised, placebo controlled, patient and observer masked study to evaluate the efficacy of treatment with Sandostatin® LAR 20 mg intramuscularly (i.m.) or placebo every 4 weeks during 6 months in 120 patients with exudative age-related macular degeneration

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
20/12/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
20/12/2005	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
04/11/2008	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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Additional identifiers

Protocol serial number

CSMS995IB01; (local study number: OZR-1999-14); NTR331

Study information

Scientific Title

Study objectives

Sandostatin® LAR administered intramuscularly (i.m.) at a dose of 20 mg once per 4 weeks during 6 months, to patients with exudation in age-related macular degeneration (AMD), maintains stable visual acuity, and decreases macular oedema and neovascularisation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Exudative age-related macula degeneration (AMD)

Interventions

Intramuscular injection of 20 mg Sandostatin® LAR or standard 0.9% saline solution once every 4 weeks during 6 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sandostatin® LAR

Primary outcome(s)

1. Visual acuity and contrast sensitivity
2. Decrease in macular oedema
3. Arrest of neovascularisation (FAG)

Key secondary outcome(s)

No secondary outcome measures

Completion date

21/08/2003

Eligibility

Key inclusion criteria

1. Recent history of visual acuity decrease (less than 6 weeks prior to study start) related to exudative AMD
2. Clinical signs of AMD (i.e. drusen and/or retinal pigment epithelium [RPE] changes)
3. Aged greater than 60 years
4. Fluorescein angiograms (FAG) (taken within 96 hours after randomisation) documenting fluorescein leakage from a well-demarcated classic or mixed choroidal neovascularisation (CNV) within 200 µm of the centre of the foveal avascular zone (FAZ) (size less than 3.5 disc areas)
5. Best corrected visual acuity for distance in study eye greater than or equal to 0.125 (Snellen chart) determined within 96 hours after randomisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Diabetes mellitus
2. Symptomatic cholelithiasis
3. Use of anticoagulants
4. Malignancy
5. Active hepatitis or clinically significant liver disease or dysfunction
6. Platelets less than 1011/L
7. Haemoglobin (Hb) less than 55 mmol/L
8. Concomitant surgical intervention, laser coagulation acetazolamide, systemic steroids or immunorepressive therapy
9. Tear of the RPE
10. Vitelliform-like lesion of the outer retina or central serous retinopathy
11. Additional ocular disease which has irreversibly compromised, or is likely to compromise during follow-up, visual acuity of the study eye
12. Inability to obtain photographs to document CNV
13. History of CNV treatment in study eye
14. Participation in another ophthalmic clinical trial
15. Intraocular surgery within previous two months
16. Neodymium-doped yttrium aluminium garnet (Nd:YAG) capsulometry within last month

Date of first enrolment

02/02/2000

Date of final enrolment

21/08/2003

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

Industry

Funder Name

Novartis Pharma B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration