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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25954

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

Visual acuity and contrast sensitivity,
decrease in macular edema and arrest of neovascularisation (FAG).

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

Sandostatin LAR administered i.m. at a dose of 20 mg once per 4 weeks during 6 months, to patients with exudation in AMD, maintains stable visual acuity, and decreases macular edema and neovascularisation.

Study design

N/A

Intervention

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

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Eligibility criteria

Inclusion criteria

1. Recent history of visual acuity decrease (< 6 weeks prior to study start) related to exudative ARMD;

2. Clinical signs of ARMD (i.e. drusen and/or RPE changes);

3. Age > 60 years;

4. FAG (taken within 96 hrs after randomization) documenting fluorescin leakage from a well-demarcated classic or mixed CNV within 200 ¦Ìm of the center of the FAZ (size < 3.5 disc areas);

5. Best corrected visual acuity for distance in study eye ¡Ý 0.125 (Snellen chart) determined within 96 hrs after randomization.

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 < 1011/L;

7. Hb < 5.5 mmol/L;

8. Concomittant surgical intervention, laser coagulation, acetazolamide, systemic steroids or immunorepressive therapy,
tear of the RPE;

9. Vitelliform-like lesion of the outer retina or central serous retinopathy;

10. Additional ocular disease which has irreversibly compromised, or is likely to compromise during follow-up, visual acuity of the study eye;

11. Inabillity to obtain photographs to document choroidal neovascularization, history of CNV treatment in study eye;

12. Participation in another ophthalmic clinical trial;

13. Intraocular surgery within previous 2 months;

14. Nd:YAG capsulometry within last month.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2000
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	11-10-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL293
NTR-old	NTR331
Other	: CSMS995IB01; (local study number: OZR-1999-14)
ISRCTN	ISRCTN16381123

Study results

Summary results
T.Missotten, G.S. Baarsma, R.W. A. M. Kuijpers, P.M. van Hagen. Somatostatin Analog for the Treatment of Exsudative Age Related Macular Degeneration: A Randomised Trial. ARVO 2007.