ISRCTN16381123 https://doi.org/10.1186/ISRCTN16381123

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
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
04/11/2008

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
02/02/2000

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

Age group
Senior

Sex
Both

Target number of participants
120 (study closed, analysis and publication in progress)

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)

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02hjc7j46

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V. (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