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Recombinant tissue Plasminogen Activator administration by retinal branch vein route for Central Retinal Vein Occlusion: a randomised conventional therapy controlled trial

Submission date
26/09/2006

Recruitment status
No longer recruiting

Registration date
26/09/2006

Overall study status
Completed

Last Edited
23/09/2021

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

Protocol serial number
OZR-2005-14, NL646 (NTR707)

Study information

Scientific Title
Recombinant tissue Plasminogen Activator administration by retinal branch vein route for Central Retinal Vein Occlusion: a randomised conventional therapy controlled trial

Acronym
CRVO study

Study objectives
Recombinant tissue Plasminogen Activator (rt-PA) administration by retinal branch vein way in Central Retinal Vein Occlusion (CRVO) patients improves final Best Corrected Visual Acuity (BCVA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised conventional therapy controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Central Retinal Vein Occlusion (CRVO)

Interventions
Injection of rt-PA (0.2 mg/ml, 4 ml) in retinal branch vein.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Recombinant tissue Plasminogen Activator (rt-PA)

Primary outcome(s)
BCVA on Early Treatment Diabetic Retinopathy Study (ETDRS) chart.

Key secondary outcome(s))
Reduction in:
1. Neovascular changes
2. Neovascular glaucoma
3. Rates of development of macular oedema

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Informed consent
2. Over 18 years of age
3. Adequate birth control (if not post-menopausal or sterilised) during a two week pre- and six week post-operative period if assigned to vitreoretinal surgery
4. Subjective decrease in visual acuity starting within four weeks prior to study start, due to CRVO, clinically evident by fundoscopy
5. Non-perfused or perfused CRVO with a visual acuity of less than 20/200

Note : Pseudophakic patients are allowed to participate in this study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to visualize fundus due to corneal or important lenticular opacities
2. Inability to obtain photographs of CRVO due to allergy to fluorescein or lack of veinous access
3. As visual acuity prognosis is better and risk for neovascularisation is reduced in perfused CRVO, patients with a visual acuity of more than 20/200 will not be included
4. Presence of iris neovascularisation (more than grade one) or anterior chamber angle (more than grade one) at the moment of presentation
5. Other retinal or ophthalmic disorders that could influence the macular area
6. Disorders that could be complicated by iris or retinal neovascularisation
7. Disorders that could be complicated by any form of secondary glaucoma
8. Prescription of acetazolamide or high dose systemic steroid (more than 10 mg prednisone daily) or other anti-inflammatory medication (eg. Methotrexate (MTX), Imuran, Endoxan, Humira, Kineret, Infliximab, Thalidomide) except Non Steriodal Anti-Inflammatory Drugs (NSAIDs)
9. Participation in another clinical ophthalmic trial
10. Any surgery of the orbit, ocular adnexae or eye scheduled during the period the study (except for cataract surgery, developed after inclusion to a degree as outlined by the protocol)
11. Monophthalmia or other known ophthalmic disorder in the fellow eye that could be complicated by blindness
12. Previous retinal surgery

13. High myopia (-8 D spherical equivalent or more)
14. Macula affecting drugs

Date of first enrolment
01/07/2006

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Oogziekenhuis Rotterdam
Rotterdam
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3011 BH

Sponsor information

Organisation
Oogziekenhuis Rotterdam (OZR) (The Netherlands)

ROR
https://ror.org/02hjc7j46

Funder(s)

Funder type
Research organisation

Funder Name
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