

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/09/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Condition

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 measure

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

Secondary outcome measures

Reduction in:

1. Neovascular changes
2. Neovascular glaucoma
3. Rates of development of macular oedema

Overall study start date

01/07/2006

Overall study end date

30/06/2008

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

48

Participant 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 Steroidal 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

Recruitment start date

01/07/2006

Recruitment end date

30/06/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Oogziekenhuis Rotterdam

Rotterdam

Netherlands

3011 BH

Sponsor information

Organisation

Oogziekenhuis Rotterdam (OZR) (The Netherlands)

Sponsor details

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info@oogziekenhuis.nl

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02hjc7j46>

Funder(s)

Funder type

Research organisation

Funder Name

Stichting Wetenschappelijk Onderzoek het Oogziekenhuis (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