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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

**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 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 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

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
48

### 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**
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## Sponsor information

### Organisation
Oogziekenhuis Rotterdam (OZR) (The Netherlands)

### Sponsor details

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**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