rt-PA administration by retinal branch vein route for Central Retinal Vein Occlusion (CRVO). A Randomized - Conventional Therapy controlled – Trial.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24763

Source
NTR

Brief title
CRVO study

Health condition

Central Retinal Vein Occlusion (CRVO)

Sponsors and support

Primary sponsor: Oogziekenhuis RotterdamSchiedamsevest 1803011 BH Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Intervention

Outcome measures

Primary outcome

BCVA on ETDRS chart.

Secondary outcome

Reduction in:
1. Neovascular changes;
2. Neovascular glaucoma;
3. Rates of development of macular oedema.

Study description

Background summary

Central retinal vein occlusion (CRVO) is a frequent retinal disorder. In the literature ischemic CRVO (iCRVO) and non-ischemic CRVO with an initial visual acuity of lower than 0.1 snellen have a poor chance to improve visual acuity. At this moment no curative treatment is available. Current therapy is aimed at the prevention of neovascular glaucoma.
Preliminary results by Weiss et al. suggest a benefit, i.e. improvement of visual acuity, by branch retinal vein cannulation with injection of 4 ml of 200 ìg/ml rt-PA, a potent thrombolytic agent.
In ischemic stroke or acute myocard infarction, a dose of 100 mg rt-PA is routinely administrated by IV perfusion.
In the reports using the intra-retinal vein injection of a total dose of 0.8 mg rt-PA, no extra-ocular adverse effects were noted.
However, the studies published are non-controlled, non randomised case series, in which it is unclear if spontaneous resolution of non-ischemic CRVO (with a visual acuity higher than 0.1, which is known to improve spontaneously) confounds results.
Regarding the frequency of the disease, the poor visual acuity outcome, the lack of curative treatment, and the promising results of non-controlled case series, a rigorous prospective randomized study of the described technique is indicated.
In this phase, only the patients with minimal chance of visual acuity improvement, (i.e. the patients with a initial visual acuity of less than 0.1), are included in the study. If proven satisfactory, future studies could include patients with better initial visual acuity.

Study objective

rt-PA administration by retinal branch vein way in CRVO patients improves final BCVA.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;
2. >18 years of age;
3. Adequate birth control (if not post-menopausal or sterilised) during a 2 week pre- and 6 week post-op period if assigned to vitreoretinal surgery;
4. Subjective decrease in visual acuity starting within 4 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.

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 > 20/200 will not be included;
4. Presence of iris neovascularisation (> grade 1) or anterior chamber angle (>grade 1) 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 (> 10 mg prednisone daily) or other anti-inflammatory medication (eg. MTX, Imuran, Endoxan, Humira, Kineret, Infliximab, Thalidomide) except 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-07-2006
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-06-2006
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	NL646
NTR-old	NTR707
Other	: OZR-2005-14
ISRCTN	ISRCTN58543190

Study results

Summary results
van Overdam KA, Missotten T, Spielberg LH. Updated cannulation technique for tissue plasminogen activator injection into peripapillary retinal vein for central retinal vein occlusion. Acta Ophthalmol. 2015; 93(8): 739-744.