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

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24763

Bron
NTR

Verkorte titel
CRVO study

Aandoening

Central Retinal Vein Occlusion (CRVO)

Ondersteuning

Primaire sponsor: Oogziekenhuis RotterdamSchiedamsevest 1803011 BH Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

BCVA on ETDRS chart.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL646
NTR-old	NTR707
Ander register	: OZR-2005-14
ISRCTN	ISRCTN58543190

Resultaten

Samenvatting resultaten
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.