Intravitreal versus submacular injection of rtPA for acute submacular haemorrhages.

Gepubliceerd: 19-03-2012 Laatst bijgewerkt: 18-08-2022

Submacular administration of rtPA for submacular haemorrhages is safe and effective.

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

Samenvatting

ID

NL-OMON25583

Bron
Nationaal Trial Register

Aandoening

Acute submacular haemorrhages.

Ondersteuning

Primaire sponsor: The Rotterdam Eye Hospital
PO Box 70030
3000 LM Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek Oogziekenhuis ¡§C Prof. Dr. Flieringa (SWOO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Location of haemorrhage at baseline and 6 weeks;
2. Size of haemorrhage at baseline and 6 weeks;

3. Safety at 6 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Submacular haemorrhage (SMH) is a severe complication of age-related macular degeneration (AMD). Anti-VEGF injections, the current standard treatment for exudative AMD, appear to be ineffective when a (large) SMH is present. If untreated, the SMH itself will cause irreversible damage to the retina and retinal pigment epithelium (RPE). Two treatment modalities of SMH will be compared.

Objective:

To examine which administration route of recombinant tissue plasminogen activator (rtPA) is safe and effective.

Study design:

Prospective, randomized, explorative intervention study.

Study population:

Consecutive patients with SMH existing ¡Ü 14 days at time of surgery.

Intervention:

Study arm 1: Submacular rtPA with pars plana vitrectomy (ppV), intravitreal C3F8/air mixture and bevacizumab.

Study arm 2: Intravitreal rtPA, C3F8 gas and bevacizumab.

Main study parameters:

Location and size of haemorrhage at 6 weeks.

Safety, Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

It is not clear, in advance, whether intravitreal or subretinal administration of rtPA is superior with respect to efficacy and safety. It is assumed that the minimally invasive treatment has a smaller effect on resorption and/or relocation of the blood but involves a lower risk of complications, while the maximally invasive treatment has a stronger effect on the SMH but involves a higher risk of complications. There will be 7 visits involving study-related assessments for both study arms: i.e. pre-operative, surgery, post-operative day 1, week 2, 4, 6, 12.

Doel van het onderzoek

Submacular administration of rtPA for submacular haemorrhages is safe and effective.

Onderzoeksopzet

Baseline, day 0, day 1, weeks 2, 4, 5, 6, 10 and 12.

Onderzoeksproduct en/of interventie

Study arm 1: Submacular rtPA with pars plana vitrectomy, intravitreal C3F8/air mixture and bevacizumab.

Study arm 2: Intravitreal rtPA, C3F8 gas and bevacizumab.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent;

2. Age > 45;

3. Submacular haemorrhage not existing longer than 14 days at time of surgery;

4. A clinically relevant SMH that needs treatment;

5. If patient is on anticoagulant drugs: INR<2 (measured during preoperative holding).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. INR>2 (or when treating cardiologist does not allow an INR<2);

2. Known etiology of SMH other than exudative AMD;

3. Known serious allergy to fluorescein or indocyanine green dye;

4. Immunocompromised.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-03-2012
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	NL3208

Register	ID
NTR-old	NTR3359
Ander register	METC OZR / CCMO : 2010-22 / NL34560.078.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

de Jong JH, van Zeeburg EJ, Cereda MG, van Velthoven ME, Faridpooya K, Vermeer KA, van Meurs JC. Intravitreal versus subretinal administration of recombinant tissue plasminogen activator combined with gas for acute submacular hemorrhages due to age-related macular degeneration: An Exploratory Prospective Study. Retina. 2016; 36(5): 914-925