Intravitreal versus submacular injection of rtPA for acute submacular haemorrhages.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25583

Source
Nationaal Trial Register

Health condition

Acute submacular haemorrhages.

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital
PO Box 70030
3000 LM Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis ¡§C Prof. Dr. Flieringa (SWOO)

Intervention

Outcome measures

Primary outcome

1. Location of haemorrhage at baseline and 6 weeks;

2. Size of haemorrhage at baseline and 6 weeks;

3. Safety at 6 weeks.

Secondary outcome

1. Location and size of haemorraghe at 12 weeks (at ophthalmologists' discretion);

2. Visual acuity (ETDRS chart) at baseline 6 and 12 weeks.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

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

Contacts

Public
Oogziekenhuis Rotterdam,
Schiedamsevest 180
J.C. Meurs, van

Schiedamsevest 180
Rotterdam 3011 BH
The Netherlands
+31 (0)10 4017777
Scientific
Oogziekenhuis Rotterdam,
Schiedamsevest 180
J.C. Meurs, van
Schiedamsevest 180
Rotterdam 3011 BH
The Netherlands
+31 (0)10 4017777

Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	19-03-2012
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	NL3208

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

Study results

Summary results

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