A Randomized, Sham-Injection Controlled, Double-Masked, Ascending-Dose, Dose-Range-Finding Trial of Microplasmin Intravitreal Injection for Non-Surgical PVD Induction for Treatment of Diabetic Macular Edema.

Published: 15-01-2007
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The purpose of this study is to evaluate if microplasmin is safe and effective when injected into the vitreous without performing a vitrectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON34009

Source
ToetsingOnline

Brief title
MIVI II

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Diabetic eye disease/Retinal disease

Research involving
Human

Sponsors and support

Primary sponsor: Thrombogenics N.V.
Source(s) of monetary or material Support: ThromboGenics Ltd.

Intervention

Keyword: Diabetic Macular Edema, intravitreal, Microplasmin, Posterior Vitreal Detachment

Outcome measures

Primary outcome

The number of patients with a total posterior vitreous detachment induced 14

days post-injection.

Secondary outcome

- Proportion of patients with total posterior vitreous detachment

- Macular Edema resolution

- Change in Best Corrected Visual Activity (the abillity to see letters on a

chart in front and to the side of the patient without moving the eyes).

- Achievement and time to improve the Best Corrected Visual Activity

- Maintenance of gain in vision

- Moderate/sustained/severe visual lost and time to obtain visual lost

- VFQ-25 questionnaire

- Need for alternative therapy

- Progression of severity of diabetic retinopathy

Study description

Background summary

The vitreous is an approximately spherical transparent gel like structure that

is attached in the back of the eye to the retina (the light sensitive part of the eye responsible for vision). Certain eye diseases, like diabetic retinopathy, may be associated with the vitreous pulling on the retina. This can result in problems with vision and other complications. An option for treatment is a specific type of eye surgery called a vitrectomy (surgery to loosen and remove the vitreous from the retina. However this surgery can be difficult and there may be complications that limit its usefulness and/or outcome.

Microplasmin is an experimental drug that will be tested to evaluate if its injection in the vitreous will induce a total posterior vitreous detachment, loosening the connection between the vitreous and the retina. Detachment of the vitreous from the retina may improve certain retinal conditions, such as diabetic retinopathy or diabetic macular edema.

Study objective

The purpose of this study is to evaluate if microplasmin is safe and effective when injected into the vitreous without performing a vitrectomy.

Study design

This trial will investigate 3 doses of microplasmin: 25, 75 and 125 µg, in 3 successive groups of patients. The patients in each group will be randomized to active treatment or sham-injection.

Intervention

Injection with microplasmin in the vitreous of the study eye.

Study burden and risks

After the injection patients need to return to the hospital for a number of 10 follow-up examinations. During these visits patients receive a full eye examination.
The risks associated to the injection are low, and potential complications can be treated effectively by antibiotics or a vitrectomy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Male or female patients aged >= 18;
• Patients with DME (Diabetic Macular Edema) involving the center of the macula with a macular thickness (in the central subfield on OCT (Ocular Coherence Tomography) of greater than 275 microns in the study eye;
• No evidence in study eye of complete macular PVD (Posterior Vitreous Detachment) (on biomicroscopy, B-scan or OCT), i.e. attached posterior hyaloid or incomplete PVD with vitreomacular adhesions;
• BCVA (Best Corrected Visual Activity) of 20/32 or worse in study eye;
• BCVA of 20/400 or better in the contralateral eye;
• Written informed consent obtained from the patient prior to inclusion in the study.

Exclusion criteria

• Evidence of fibrocellular proliferation characterized by whitish epimacular tissue (surface wrinkling is not an exclusion criterion) in the study eye;
• Evidence of foveal ischemia (foveal avascular zone: longest diameter > 1,000 microns) or dense, hard exudates beneath the fovea;
• Evidence of complete macular PVD in study eye on biomicroscopy, B-scan or OCT prior to

planned study drug injection;
• Any evidence of proliferative retinopathy meeting the definition for PDR (Proliferative Diabetic Retinopathy) in the study eye;
• Patients with vitreous hemorrhage which precludes either of the following: visualization of the posterior pole by visual inspection OR adequate assessment of the macula by either OCT and/or fluorescein angiogram in the study eye;
• Patients with rhegmatogenous retinal detachment, PVR, or retinal degenerative changes associated with increased risk of retinal detachment in the study eye. Such retinal degenerative changes include lattice degeneration or cystic retinal tufts. Thorough retinal examination should be performed in all patients to rule out these changes.
• Patients with high myopia (axial length > 26.0 mm on A-scan ultrasound) or aphakia in the study eye;
• Patients with history of rhegmatogenous retinal detachment in the fellow eye;
• Patients who are considered likely to require intraocular surgery in either eye for any reason in the coming three months;
• Patients who have had ocular surgery in the study eye in the prior three months;
• Patients who have had a vitrectomy in study eye at any time;
• Patients with glaucoma that is not controlled with topical medication or that is associated with severe visual field loss documented by perimetry in the study eye;
• Patients who have had laser photocoagulation treatment in the study eye in the previous 3 months;
• Intravitreal injection of any drug in the study eye in the previous 3 months
• Patients who are pregnant or of child-bearing potential not utilizing a form of contraception acceptable to the Investigator;
• Patients who in the investigators view will not complete all visits and investigations, including the last double-masked visit at 6 months;
• Patients who have participated in an investigational drug study within the past 30 days;
• Patients with poor glycemic control according to the Investigator;
• Patients with hypertension (either Systolic Blood Pressure > 170 or Diastolic Blood Pressure > 100 mm Hg);
• Patients with a life expectancy less than 6 months;
• Patients who have previously participated in this trial.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2007
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	microplasmin
Generic name:	microplasmin

Ethics review

Approved WMO Date:	15-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-10-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-01-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	20-02-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-04-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-03-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-08-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-09-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2006-004626-93-NL
CCMO	NL14389.078.06