An Open-Label, Ascending-Exposure-Time, Single Center Trial to Evaluate the Pharmacokinetic Properties of Ocriplasmin (Generic Name of the Molecule Microplasmin) Intravitreal Injection in Subjects Scheduled for Primary Pars Plana Vitrectomy) (MIVI-10)

This study has been completed.

Sponsor:	Thrombogenics
Collaborators:	
Information provided by (Responsible Party):	Thrombogenics
ClinicalTrials.gov Identifier:	NCT01159665

Purpose

The primary objective of the study is to evaluate the Pharmacokinetic Properties of Intravitreal Ocriplasmin Prior to Planned Primary Pars Plana Vitrectomy (PPV) (MIVI-10)
Secondary objectives: not provided

Condition	Intervention	Phase
Vitrectomy	Drug: Ocriplasmin	Phase 2

Study type: interventional
Study design: Treatment, Parallel Assignment, Open label, Non-Randomized, Pharmacokinetics Study

Official Title

An Open-Label, Ascending-Exposure-Time, Single Center Trial to Evaluate the Pharmacokinetic Properties of Ocriplasmin (Generic Name of the Molecule Microplasmin) Intravitreal Injection in Subjects Scheduled for Primary Pars Plana Vitrectomy

Further study details as provided by ThromboGenics:

Primary Outcome Measures:

- Ocriplasmin Activity Levels in Vitreous Samples Obtained at the Beginning of Vitrectomy. [Time Frame: 5-30 minutes, 31-60 minutes, 2-4 hours, 1 day, or 7 days after ocriplasmin injection] [Designated as safety issue: No]

  Vitreous samples were obtained at the beginning of vitrectomy in subjects at various times relative to ocriplasmin injection (post-injection), for the determination of ocriplasmin activity (Group 1 [5-30 minutes]; Group 2 [31-60 minutes]; Group 3 [2-4 hours]; Group 4 [24 hours ±2 hours]; Group 5 [7 days ±1 day]. Subjects in Group 6 (control) did not receive the ocriplasmin injection

Other Outcome Measures:

- Time Necessary to Remove the Vitreous From the Eye [Time Frame: From first start of vitrectomy cutter till the end of core vitrectomy phase] [Designated as safety issue: No]

  PPV was performed in all subjects. The time necessary to remove the vitreous from the eye, measured from first start of vitrectomy cutter till end of core vitrectomy phase, was calculated

Enrollment: 38
Study Start Date: July 2010
Primary Completion Date: November 2010 (Final data collection date for primary outcome measure)
Study Completion Date: January 2011

Arms	Assigned Interventions
Experimental: PPV 5-30 minutes after injection Primary Pars Plana Vitrectomy 5 to 30 minutes after 125µg of ocriplasmin intravitreal injection	Drug: Ocriplasmin 125µg ocriplasmin intravitreal injection Other Name: Microplasmin
Experimental: PPV 31-60 minutes after injection Primary Pars Plana Vitrectomy 31 to 60 minutes after 125µg of ocriplasmin intravitreal injection	Drug: Ocriplasmin 125µg ocriplasmin intravitreal injection Other Name: Microplasmin
Experimental: PPV 2-4 hours after injection Primary Pars Plana Vitrectomy 2 to 4 hours after 125µg of ocriplasmin intravitreal injection	Drug: Ocriplasmin 125µg ocriplasmin intravitreal injection Other Name: Microplasmin
Experimental: PPV 24 hours (± 2 hours) after injection Primary Pars Plana Vitrectomy 24 hours (± 2 hours)after 125µg of ocriplasmin intravitreal injection	Drug: Ocriplasmin 125µg ocriplasmin intravitreal injection Other Name: Microplasmin
Experimental: PPV 7 days (± 1 day) after injection Primary Pars Plana Vitrectomy 7 days (±1 day)after 125µg of ocriplasmin intravitreal injection	Drug: Ocriplasmin 125µg ocriplasmin intravitreal injection Other Name: Microplasmin

Detailed Description:

- Open-label, ascending-exposure-time, single center trial in which a total of 36 subjects will be enrolled. The time to remove the vitreous will be recorded and a vitreous sample will be obtained at the beginning of vitrectomy for determination of ocriplasmin activity; 32 subjects will receive 125 µg ocriplasmin intravitreal injection prior to vitrectomy and 4 subjects will not receive ocriplasmin intravitreal injection prior to vitrectomy (control arm)
- Study drug will be administered in the mid-vitreous by injection. The study eye will be examined after study drug injection to exclude retinal non-perfusion or other complications

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Male or female subjects aged ≥ 18
- Eye disease for which a primary vitrectomy is indicated
- Best Corrected Visual Acuity (BCVA) of 20/800 or better in the non-study eye
- Written informed consent obtained from the subject prior to inclusion in the trial

Exclusion Criteria:

- Proliferative diabetic retinopathy
- Subjects with any vitreous hemorrhage or any other vitreous opacification which precludes either of the following: visualization of the posterior pole by visual inspection OR adequate assessment of the macula by either Optical Coherence Tomography (OCT) and/or fluorescein angiogram in the study eye
- Aphakia in the study eye
- High myopia (more than 8D) in study eye (unless prior cataract extraction or refractive surgery that makes refraction assessment unreliable for myopia severity approximation, in which case axial length >28 mm is an exclusion).
- Subjects with history of rhegmatogenous retinal detachment in either eye
- Subjects who have had ocular surgery, laser photocoagulation treatment, or intravitreal injection(s) in the study eye in the prior three months
- Subjects who have had laser photocoagulation to the macula in the study eye at any time
- Subjects with uncontrolled glaucoma in the study eye (defined as intraocular pressure ≥ 26 mm Hg in spite of treatment with anti-glaucoma medication)
- Subjects with a history of uveitis in either eye
- Subjects who are pregnant or of child-bearing potential not utilizing an acceptable form of contraception. Acceptable methods of birth control include intrauterine device, oral, implanted, or injected contraceptives, and barrier methods with spermicide
- Subjects who, in the Investigators view, will not complete all visits and investigations
- Subjects who have participated in an investigational drug trial within the past 30 days
- Subjects who have previously participated in this trial

Contacts and Locations

Locations

Belgium

University Hospital Leuven

Leuven, Belgium, B-3000

sponsors and collaborators

ThromboGenics

More Information

Responsible Party: ThromboGenics
Other Study ID Numbers: TG-MV-010
ClinicalTrials.gov Identifier: NCT01159665

EudraCT: 2010-018919-16

Health Authority: Belgium: Federal Agency for Medicinal Products and Health Products

Participant Flow

Pre-Assignment Details

38 subjects were enrolled into the study. However, the vitreous samples for 2 subjects were excluded from the analysis:

The vitreous sample for Subject 101106 was contaminated during vitrectomy.

Subject 101202 (Group 2) had a previous vitrectomy and retinal detachment in the study eye (exclusion criteria violation)

Recruitment Details

The first subject was enrolled on 15 Jul 2010 and the last patient completed the study on 30 Nov 2010

Study Results

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (± 2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (±2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (± 1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (±1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

Participant Flow: Overall Study

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 Hours After Injection	PPV 24 Hours (±2 Hours) After Injection	PPV 7 Days (±1 Day) After Injection	PPV Without Injection
STARTED	**9**	**9**	**8**	**4**	**4**	**4**
COMPLETED	**9**	**8**	**8**	**4**	**4**	**4**
NOT COMPLETED	**0**	**1**	**0**	**0**	**0**	**0**
Withdrawal by Subject	**0**	**1**	**0**	**0**	**0**	**0**

Baseline Characteristics

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (±2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (± 2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (±1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (± 1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

Baseline Measures

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 Hours After Injection	PPV 24 Hours (±2 hours) after injection	PPV 7 Days (±1 Day) after injection	Injection Without PPV	Total
Number of Participants [units: participants]	**9**	**9**	**8**	**4**	**4**	**4**	**38**
Age [units: years] Mean (Standard Deviation)	**71.3 (8.56)**	**65.6 (13.50)**	**63.8 (9.38)**	**62.5 (8.66)**	**59.3 (11.87)**	**69.8 (7.80)**	**66.0 (10.5)**
Gender [units: participants]							
Female	**7**	**6**	**6**	**3**	**1**	**3**	**26**
Male	**2**	**3**	**2**	**1**	**3**	**1**	**12**

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Ocriplasmin Activity Levels in Vitreous Samples Obtained at the Beginning of Vitrectomy.
Measure Description	Vitreous samples were obtained at the beginning of vitrectomy in subjects at various times relative to ocriplasmin injection (post-injection), for the determination of ocriplasmin activity (Group 1 [5-30 minutes]; Group 2 [31-60 minutes]; Group 3 [2-4 hours]; Group 4 [24 hours ±2 hours]; Group 5 [7 days ±1 day]. Subjects in Group 6 (control) did not receive the ocriplasmin injection.
Time Frame	5-30 minutes, 31-60 minutes, 2-4 hours, 1 day, or 7 days after ocriplasmin injection
Safety Issue?	No

Analysis Population Description

Safety Set. Values for the PPV 7 days (± 1 day) after injection and for PPV without injection treatment groups were all < Lower Limit of Quantification

(LLOQ)

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (±2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (±2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (±1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (±1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

Measured Values

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 Hours After Injection	PPV 24 Hours (±2 Hours) After Injection	PPV 7 Days (±1 Day) After Injection	PPV Without Injection
Number of Participants Analyzed [units: participants]	**8**	**8**	**8**	**4**	**4**	**4**
Ocriplasmin Activity Levels in Vitreous Samples Obtained at the Beginning of Vitrectomy. [units: ng/mL] Mean (Standard Deviation)	**11597.711 (7637.4103)**	**8108.726 (5181.8506)**	**2610.563 (1608.2660)**	**496.473 (288.2498)**	**272.370 (0.00)**	**272.370 (0.00)**

No statistical analysis provided for Ocriplasmin Activity Levels in Vitreous Samples Obtained at the Beginning of Vitrectomy.

2. Other pre-specified:

Measure Title	Time Necessary to Remove the Vitreous From the Eye [Time Frame: From first start of vitrectomy cutter till the end of core vitrectomy phase]
Measure Description	PPV was performed in all subjects. The time necessary to remove the vitreous from the eye, measured from first start of vitrectomy cutter till end of core vitrectomy phase, was calculated.
Time Frame	From first start of vitrectomy cutter till the end of core vitrectomy phase
Safety Issue?	No

Analysis Population Description: Safety Set.

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (±2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (± 2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (±1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (± 1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

Measured Values

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 hours after Injection	PPV 24 Hours (±2 Hours) After Injection	PPV 7 Days (±1 Day) After Injection	PPV without injection
Number of Participants Analyzed [units: participants]	9	6	7	2	2	4
Time Necessary to Remove the Vitreous From the Eye [units: Minutes] Mean (Standard Deviation)	4.2 (3.07)	3.7 (2.88)	5.1 (1.86)	4.5 (2.12)	4.0 (1.41)	4.8 (2.06)

No statistical analysis provided for Time Necessary to Remove the Vitreous From the Eye

Reported Adverse Events

Time Frame	Adverse Events (AEs) were collected from study drug administration through last subject follow-up visit (49 days (± 3 days) post-surgery)
Additional Description	Only treatment emergent AEs, defined as events with an onset on or after the date of study drug injection were included in the AE summaries. For the control arm (Group 6), AEs on or after the Baseline visit were considered treatment emergent in order to compare with the treatment groups.

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (±2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (± 2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (±1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (± 1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

Serious Adverse Events

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 Hours After Injection	PPV 24 Hours (±2 Hours) After Injection	PPV 7 Days (± 1 Day) After Injection	PPV Without Injection
Total, serious adverse events						
# participants affected / at risk	**1/9 (11.11%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**	**2/4 (50.00%)**
Cardiac disorders						
Cardiac failure congestive † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Eye disorders						
Choroidal Haemorrhage † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Hyphaema † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Vitreous Haemorrhage † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**

Neoplasms benign, malignant **and unspecified (incl cysts** and **polyps)**						
Paraneoplastic syndrome † 1						
# participants affected / at **risk**	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**	**0/4** (0.00%)
# events	**0**	**0**	**0**	**0**	**1**	**0**
Respiratory, thoracic and **mediastinal disorders**						
Respiratory failure † 1						
# participants affected / at **risk**	**1/9 (11.11%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4** (0.00%)
# events	**1**	**0**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.1

Other Adverse Events

Time Frame	Adverse Events (AEs) were collected from study drug administration through last subject follow-up visit (49 days (± 3 days) post-surgery).
Additional Description	Only treatment emergent AEs, defined as events with an onset on or after the date of study drug injection were included in the AE summaries. For the control arm (Group 6), AEs on or after the Baseline visit were considered treatment emergent in order to compare with the treatment groups.

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
PPV 5-30 Minutes After Injection	Primary Pars Plana Vitrectomy 5 to 30 minutes after 125ug of ocriplasmin intravitreal injection
PPV 31-60 Minutes After Injection	Primary Pars Plana Vitrectomy 31 to 60 minutes after 125ug of ocriplasmin intravitreal injection
PPV 2-4 Hours After Injection	Primary Pars Plana Vitrectomy 2 to 4 hours after 125ug of ocriplasmin intravitreal injection
PPV 24 hours (±2 hours) After Injection	Primary Pars Plana Vitrectomy 24 hours (± 2 hours) after 125ug of ocriplasmin intravitreal injection
PPV 7 Days (±1 Day) After Injection	Primary Pars Plana Vitrectomy 7 days (± 1 day)after 125ug of ocriplasmin intravitreal injection
PPV Without Injection	Control Arm, no ocriplasmin intravitreal injection

	PPV 5-30 Minutes After Injection	PPV 31-60 Minutes After Injection	PPV 2-4 Hours After Injection	PPV 24 Hours (± 2 Hours) After Injection	PPV 7 Days (± 1 Day) After Injection	PPV Without Injection
Total, other (not including serious) adverse events						
# participants affected / at risk	2/9 (22.22%)	5/9 (55.56%)	5/8 (62.50%)	4/4 (100.00%)	4/4 (100.00%)	3/4 (75.00%)
Eye disorders						
Photopsia † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	1/4 (25.00%)	4/4 (100.00%)	0/4 (0.00%)
# events	0	0	0	1	4	0
Visual acuity reduced † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	3/4 (75.00%)	4/4 (100.00%)	0/4 (0.00%)
# events	0	0	0	3	4	0
Vitreous floaters † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	3/4 (75.00%)	4/4 (100.00%)	0/4 (0.00%)
# events	0	0	0	3	4	0
Chromatopsia † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	2/4 (50.00%)	2/4 (50.00%)	0/4 (0.00%)
# events	0	0	0	2	2	0
Cataract cortical † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0

Conjunctival haemorrhage †						
1 # participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0
Corneal erosion † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
# events	0	0	0	0	0	1
Eye pain † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	1/4 (25.00%)	0/4 (0.00%)	0/4 (0.00%)
# events	0	0	0	1	0	0
Hypotony of eye † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0
Macular oedema † 1						
# participants affected / at risk	0/9 (0.00%)	1/9 (11.11%)	2/8 (25.00%)	0/4 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
# events	0	1	2	0	0	0
Metamorphopsia † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0
Photophobia † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0
Pupillary deformity † 1						
# participants affected / at risk	0/9 (0.00%)	0/9 (0.00%)	0/8 (0.00%)	0/4 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
# events	0	0	0	0	1	0

Retinal artery occlusion † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Retinal oedema † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**
Retinal tear † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Blepharitis † 1						
# participants affected / at risk	**1/9 (11.11%)**	**0/9 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**1**	**0**	**0**	**0**
Dry eye † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**
Eye irritation † 1						
# participants affected / at risk	**1/9 (11.11%)**	**0/9 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**1**	**0**	**0**	**0**
Lens dislocation † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**0**	**0**	**2**	**0**	**0**	**0**

Gastrointestinal disorders						
Nausea † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Infections and infestations						
Eye infection † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**0**	**0**	**0**	**2**	**0**	**0**
Urinary tract infection † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**
Dacryocistitis † 1						
# participants affected / at risk	**0/9 (0.00%)**	**1/9 (11.11%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**0**	**2**	**0**	**0**	**0**	**0**
Injury, poisoning and procedural complications						
Procedural pain † 1						
# participants affected / at risk	**0/9 (0.00%)**	**1/9 (11.11%)**	**0/8 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**
Investigations						
Intraocular pressure increased † 1						
# participants affected / at risk	**2/9 (22.22%)**	**2/9 (22.22%)**	**2/8 (25.00%)**	**3/4 (75.00%)**	**2/4 (50.00%)**	**2/4 (50.00%)**
# events	**2**	**3**	**2**	**3**	**3**	**2**

Nervous system disorders						
Headache † 1						
# participants affected / at risk	**0/9 (0.00%)**	**0/9 (0.00%)**	**1/8 (12.50%)**	**1/4 (25.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
# events	**0**	**0**	**1**	**1**	**2**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.1

Limitations and Caveats

[Not specified]

More Information

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Publications:

Stalmans P, Girach A. Vitreous levels of active ocriplasmin following intravitreal injection: results of an ascending exposure trial. Invest Ophthalmol Vis Sci. 2013 Oct 9;54(10):6620-7. doi: 10.1167/iovs.13-11811

Results Point of Contact:

Name/Title: Dr. Petra Kozma-Wiebe
Organization: ThromboGenics
phone: +32 16751310
e-mail: Petra.kozma@thrombogenics.com