A Study to Compare Multiple Doses Intravitreal Microplasmin for Treatment of Patients With Vitreomacular Traction (MIVI-IIt)

The TG-MV-004 Trial

This study has been completed.

Sponsor:
ThromboGenics

ClinicalTrials.gov Identifier:
NCT00435539

Purpose

A multicenter study to compare multiple doses of intravitreal microplasmin for non-surgical PVD induction for treatment of patients with vitreomacular traction.

Condition	Intervention	Phase
Vitreomacular Traction	Drug: ocriplasmin Drug: Sham Comparator	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Sham-Injection Controlled, Double-Masked, Ascending-Dose, Dose-Range-Finding Trial of Microplasmin Intravitreal Injection for Non-Surgical Posterior Vitreous Detachment (PVD) Induction for Treatment of Vitreomacular Traction (VMT).

Further study details as provided by ThromboGenics

Primary Outcome Measures:

Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging. [Time Frame: Day 14] [Designated as safety issue: No]

Secondary Outcome Measures:

Resolution of Vitreomacular Traction (Investigator's Assessment) [Time Frame: Day 28] [Designated as safety issue: No]

Resolution of VMT was evaluated by the investigator using optical coherence tomography (OCT).Resolution of VMT was defined as a change from baseline status of Yes to post-injection status of No and was evaluated by the investigator using OCT. Subjects undergoing vitrectomy had their last observation prior to vitrectomy carried forward.

Enrollment: 60
Study Start Date: February 2007
Study Completion Date: February 2009
Primary Completion Date: January 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: ocriplasmin 75µg single injection Ocriplasmin 75µg single injection versus sham injection	Drug: ocriplasmin Intravitreal injection of ocriplasmin solution containing 75µg of ocriplasmin. Other Name: microplasmin
Experimental: ocriplasmin 125µg single injection Ocriplasmin 125µg single injection versus sham injection	Drug: ocriplasmin Intravitreal injection of ocriplasmin solution containing 75µg of ocriplasmin. Other Name: microplasmin
Experimental: ocriplasmin 175µg single injection Ocriplasmin 175µg single injection versus sham injection	Drug: ocriplasmin Intravitreal injection of ocriplasmin solution containing 75µg of ocriplasmin. Other Name: microplasmin
Experimental: ocriplasmin 125µg multiple injections Ocriplasmin 125µg multiple injections. Subjects who did not achieve resolution of VMT by the day 28 visit (i.e. non-responders) were given an open-label injection of ocriplasmin 125µg. Subjects who still did not achieve resolution of VMT by the day 56 visit were given a second open-label injection of ocriplasmin 125µg.	Drug: ocriplasmin Intravitreal injection of ocriplasmin solution containing 125µg of ocriplasmin with up to 2 additional (open label) 125µg ocriplasmin injection at 1 month interval. Other Name: microplasmin
Sham Comparator: sham injection sham injection	Drug: Sham Comparator Intravitreal sham injection Other Name: microplasmin

Eligibility

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

Criteria

Inclusion Criteria:

Patients ≥ 18 years of age with vitreomacular traction

Exclusion Criteria:

- PVD present at baseline
- Certain vitreoretinal conditions including proliferative disease, rhegmatogenous retinal detachment, and proliferative vitreoretinopathy (PVR)
- Vitreous hemorrhage
- Patients who have had a vitrectomy in the study eye at any time

Contacts and Locations

Locations

Belgium

ZNA OCMW Antwerpen
Antwerpen, Belgium, 2020

University Hospital of Ghent
Ghent, Belgium, B-9000

Universitaire Ziekenhuizen K.U.Leuven
Leuven, Belgium

Germany

Augenklinik der Universitat Munchen
Munchen, Germany, 80336

Sponsors and Collaborators

ThromboGenics

More Information

Responsible Party:	ThromboGenics
ClinicalTrials.gov Identifier	NCT00435539
Other Study ID Numbers:	**TG-MV-004** MIVI-IIT
Eudra CT Number:	2006-006085-42
Study First Received:	February 14, 2007
Results First Received:	July 4, 2013
Last Updated:	December 2, 2014
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP Germany: Federal Institute for Drugs and Medical Devices

Participant Flow

Recruitment Details

The first patient was enrolled on 2 March 2007 and the last patient completed the last visit on 8 January 2009. All patients were selected in medical clinics

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
All subjects in all cohorts had a similar follow-up schedule to the day 28 post-injection visit. After day 28, non-responders in cohort 4 received up to 2 repeated injections and thus had a different study follow-up schedule than all other subjects.

Reporting Groups

	Description
Ocriplasmin 75µg Single Injection	Ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 125µg Single Injection	ocriplasmin 125µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Multiple Injections	ocriplasmin 125µg multiple injections. Subjects who did not achieve resolution of VMT by the day 28 visit (i.e. non-responders) were given an open-label injection of ocriplasmin 125 µg. Subjects who still did not achieve resolution of VMT by the day 56 visit were given a second open-label injection of ocriplasmin 125 µg.
Sham Injection	sham injection

Participant Flow: Overall Study

	Ocriplasmin 75µg Single Injection	Ocriplasmin 125µg Single Injection	Ocriplasmin 175µg Single Injection	Ocriplasmin 125µg Multiple Injections	Sham Injection
STARTED	**12**	**13**	**11**	**12**	**12**
COMPLETED	**12**	**13**	**11**	**12**	**12**
NOT COMPLETED	**0**	**0**	**0**	**0**	**0**

Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Ocriplasmin 75µg Single Injection	ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 125µg Single Injection	ocriplasmin 125µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Multiple Injections	ocriplasmin 125µg multiple injections Subjects who did not achieve resolution of VMT by the day 28 visit (i.e. non-responders) were given an open-label injection of ocriplasmin 125 µg. Subjects who still did not achieve resolution of VMT by the day 56 visit were given a second open-label injection of ocriplasmin 125 µg.
Sham Injection	sham injection
Total	Total of all reporting groups

Baseline Measures

	Ocriplasmin 75µg Single Injection	**Ocriplasmin 125µg Single Injection**	**Ocriplasmin 175µg Single Injection**	**Ocriplasmin 125µg Multiple Injections**	**Sham Injection**	**Total**
Number of Participants [units: participants]	**12**	**13**	**11**	**12**	**12**	**60**
Age [units: years] Mean (Standard Deviation)	**66.58 (5.57)**	**74.67 (5.78)**	**66.11 (9.08)**	**70.61 (6.67)**	**70.28 (8.58)**	**69.79 (7.66)**
Gender [units: participants]						
Female	**8**	**8**	**4**	**7**	**6**	**33**
Male	**4**	**5**	**7**	**5**	**6**	**27**

Outcome Measures

1. Primary: Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging. [Time Frame: Day 14]

Measure Type	Primary
Measure Title	Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging.
Measure Description	No text entered.
Time Frame	Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intention to Treat (ITT)

Reporting Groups

	Description
Ocriplasmin 75µg Single Injection	Ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	Ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Pooled	Pooled data for ocriplasmin 125µg and ocriplasmin 125µg multiple injections versus sham injection
Sham Injection	sham injection

Measured Values

	Ocriplasmin 75µg Single Injection	**Ocriplasmin 175µg Single Injection**	**Ocriplasmin 125µg Pooled**	**Sham Injection**
Number of Participants Analyzed [units: participants]	**11**	**11**	**22**	**11**
Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging. [units: percentage of participants]	**18.2**	**18.2**	**13.6**	**0**

Statistical Analysis 1 for Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging.

Groups [1]	Ocriplasmin 75µg Single Injection vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.4762

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging.

Groups [1]	Ocriplasmin 175µg Single Injection vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.4762

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Proportion of Subjects With Total PVD at the First Day 14 Post-injection Visit (Vitreous Detachment to the Equator) as Determined by Masked Central Reading Center (CRC) Evaluation of B-scan Imaging.

Groups [1]	Ocriplasmin 125µg Pooled vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.5343

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: Resolution of Vitreomacular Traction (Investigator's Assessment) [Time Frame: Day 28]

Measure Type	Secondary
Measure Title	Resolution of Vitreomacular Traction (Investigator's Assessment)
Measure Description	Resolution of VMT was evaluated by the investigator using optical coherence tomography (OCT).Resolution of VMT was defined as a change from baseline status of Yes to post-injection status of No and was evaluated by the investigator using OCT. Subjects undergoing vitrectomy had their last observation prior to vitrectomy carried forward.
Time Frame	Day 28
Safety Issue	No

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique

Intention to Treat (ITT)

Reporting Groups

	Description
Ocriplasmin 75µg Single Injection	Ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	Ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Pooled	Pooled data for ocriplasmin 125µg and ocriplasmin 125µg multiple injections versus sham injection
Sham Injection	sham injection

Measured Values

	Ocriplasmin 75µg Single Injection	**Ocriplasmin 175µg Single Injection**	**Ocriplasmin 125µg Pooled**	**Sham Injection**
Number of Participants Analyzed [units: participants]	**12**	**11**	**25**	**12**
Resolution of Vitreomacular Traction (Investigator's Assessment) [units: Percentage of participants]	**25**	**27.3**	**11**	**8.3**

Statistical Analysis 1 for Resolution of Vitreomacular Traction (Investigator's Assessment)

Groups [1]	Ocriplasmin 75µg Single Injection vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.4783

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Resolution of Vitreomacular Traction (Investigator's Assessment)

Groups [1]	Ocriplasmin 175µg Single Injection vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.0932

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Resolution of Vitreomacular Traction (Investigator's Assessment)

Groups [1]	Ocriplasmin 125µg Pooled vs. Sham Injection
Method [2]	Fisher Exact
P Value [3]	0.0721

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Serious Adverse Events

Time Frame	AEs/SAEs were collected from injection day up to 6 months after injection
Additional Description	No text entered.

Reporting Groups

	Description
Ocriplasmin 75µg	Ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 125µg Single Injection	Ocriplasmin 125µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	Ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Multiple Injection	Ocriplasmin 125µg multiple injection versus sham injection
Sham Injection	Sham injection

Serious Adverse Events

	Ocriplasmin 75µg	Ocriplasmin 125µg Single Injection	Ocriplasmin 175µg Single Injection	Ocriplasmin 125µg Multiple Injection	Sham Injection
Total, serious adverse events					
# participants affected / at risk	**3/12 (25.00%)**	**2/13 (15.38%)**	**3/11 (27.27%)**	**4/12 (33.33%)**	**0/12 (0.00%)**
Cardiac disorders					
Silent Myocardial infarction † 1					
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Endocrine disorders					
Hyperthyroidism † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**0/12 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Eye disorders					
Retinal vein occlusion † 1					
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Macular hole † 1					
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**3/11 (27.27%)**	**2/12 (16.67%)**	**0/12 (0.00%)**
# events	**1**	**1**	**3**	**2**	**0**

Injury, poisoning and procedural complications					
Humerus fracture † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**0/12 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Investigations					
Intraocular pressure increased † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**0/12 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon cancer † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
Vascular disorders					
Arteriosclerosis † 1					
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

Other Adverse Events

Time Frame	AEs/SAEs were collected from injection day up to 6 months after injection
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Ocriplasmin 75µg	Ocriplasmin 75µg single injection versus sham injection
Ocriplasmin 125µg Single Injection	Ocriplasmin 125µg single injection versus sham injection
Ocriplasmin 175µg Single Injection	Ocriplasmin 175µg single injection versus sham injection
Ocriplasmin 125µg Multiple Injection	Ocriplasmin 125µg multiple injection versus sham injection
Sham Injection	Sham injection

Other Adverse Events

	Ocriplasmin 75µg	Ocriplasmin 125µg Single Injection	Ocriplasmin 175µg Single Injection	Ocriplasmin 125µg Multiple Injection	Sham Injection
Total, other (not including serious) adverse events					
# participants affected / at risk	10/12 (83.33%)	10/13 (76.92%)	10/11 (90.91%)	11/12 (91.67%)	9/12 (75.00%)
Cardiac disorders					
Dyspnoea † [1]					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Endocrine disorders					
Hypoglycaemia † [1]					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	2	0	0	0	0
Eye disorders					
Vitreous floaters † [1]					
# participants affected / at risk	4/12 (33.33%)	3/13 (23.08%)	4/11 (36.36%)	7/12 (58.33%)	0/12 (0.00%)
# events	4	3	4	9	0
Vitritis † [1]					
# participants affected / at risk	0/12 (0.00%)	3/13 (23.08%)	0/11 (0.00%)	4/12 (33.33%)	0/12 (0.00%)
# events	0	3	0	4	0
Macular hole † [1]					
# participants affected / at risk	1/12 (8.33%)	1/13 (7.69%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	1	1	0	1	0
Conjuctival hyperaemia † [1]					
# participants affected / at risk	2/12 (16.67%)	2/13 (15.38%)	1/11 (9.09%)	3/12 (25.00%)	1/12 (8.33%)
# events	2	2	1	3	1
Anterior chamber flare † [1]					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	2/12 (16.67%)	0/12 (0.00%)
# events	0	0	0	2	0
Conjunctival haemorrhage † [1]					
# participants affected / at risk	2/12 (16.67%)	1/13 (7.69%)	1/11 (9.09%)	2/12 (16.67%)	2/12 (16.67%)
# events	2	1	1	2	3
Eyelid oedema † [1]					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	2/12 (16.67%)	0/12 (0.00%)

# events	0	0	0	2	0
Eye pain † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	1/11 (9.09%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	1	1	1	0
Macular oedema † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	0	2	0	0
Macular pseudohole † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	1	1	0
Retinal haemorrhage † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	0	1	0	0
Visual acuity reduced † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	0	1	0	0
Anterior chamber cell † 1					
# participants affected / at risk	1/12 (8.33%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	1	1	0	0	0
Cataract † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Corneal oedema † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Dry eye † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	0	0	0	0	1
Keratitis † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	0	0	0	0	1
Macular scar † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Maculopathy † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	1	0	0	0	1
Meibomianitis † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	1	0	0	0	0

Optic nerve cupping † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Papilloedema † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Vitreous haemorrhage † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Vitreous opacities † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	1	0	0	0	1
Blepharitis † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Iridocyclitis † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Ocular hyperaemia † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Gastrointestinal disorders					
Abdominal rigidity † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Oesophageal stenosis † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Reflux oesophagitis † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Vomiting † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	1	0	0	0	0
Nausea † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Immune system disorders					
Hypersensitivity † 1					

# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	0	1	0	0
Systemic lupus erythematosus † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	0	0	1	0
Infections and infestations					
Nasopharyngitis † 1					
# participants affected / at risk	1/12 (8.33%)	2/13 (15.38%)	3/11 (27.27%)	1/12 (8.33%)	1/12 (8.33%)
# events	1	2	3	1	1
Influenza † 1					
# participants affected / at risk	0/12 (0.00%)	2/13 (15.38%)	1/11 (9.09%)	1/12 (8.33%)	0/12 (0.00%)
# events	0	2	1	1	0
Bronchitis † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	1/12 (8.33%)	0/12 (0.00%)
# events	1	0	0	1	0
Herpes zoster † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	0	0	0	0	1
Rhinitis † 1					
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	1	0	0	0	0
Fungal skin infection † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Sinusitis † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Tracheitis † 1					
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)	0/12 (0.00%)	0/12 (0.00%)
# events	0	1	0	0	0
Injury, poisoning and procedural complications					
Periorbital haematoma † 1					
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	0/11 (0.00%)	0/12 (0.00%)	1/12 (8.33%)
# events	0	0	0	0	1

Investigations					
Intraocular pressure increased † 1					
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**3/11 (27.27%)**	**2/12 (16.67%)**	**0/12 (0.00%)**
# events	**1**	**1**	**3**	**2**	**0**
Platelet count decreased † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**0/12 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Musculoskeletal and connective tissue disorders					
Back pain † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
Musculoskeletal pain † 1					
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Ostheoarthritis † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**0/12 (0.00%)**	**1/12 (8.33%)**
# events	**0**	**0**	**0**	**0**	**1**
Nervous system disorders					
Headache † 1					
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**1/11 (9.09%)**	**2/12 (16.67%)**	**2/12 (16.67%)**
# events	**1**	**0**	**2**	**2**	**2**
Syncope † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**	**0/12 (0.00%)**	**0/12 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
Psychiatric disorders					
Depression † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**1/12 (8.33%)**
# events	**0**	**0**	**0**	**1**	**1**
Skin and subcutaneous tissue disorders					
Psoriasis † 1					
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**0/11 (0.00%)**	**1/12 (8.33%)**	**0/12 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 10.1

Limitations and Caveats

No text entered.

Certain Agreements:

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 agreement is:

- [x] 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.
- [ ] 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 **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

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