ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **2 of 2** for: CRFB002EDE17

Previous Study | Return to List | Next Study

Efficacy and Safety of Ranibizumab Intravitreal Injections Versus Dexamethasone Intravitreal Implant in Patients With Branch Retinal Vein Occlusion (BRVO) (COMRADE-B)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01396057

First received: July 14, 2011
Last updated: August 4, 2014
Last verified: August 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: June 13, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Visual Impairment Macular Edema Branch Retinal Vein Occlusion
Interventions:	Drug: Ranibizumab Other: Dexamethasone Implant

	Other: Sham injection

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Participant Flow: Overall Study

	Ranibizumab	Dexamethasone
STARTED	**126**	**118**
COMPLETED	**115**	**100**
NOT COMPLETED	**11**	**18**
Adverse Event	**2**	**6**
Unsatisfactory therapeutic effect	**2**	**6**
Protocol deviation	**4**	**4**

Consent withdrawn	**3**	**2**

Baseline Characteristics

Hide 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
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months
Total	Total of all reporting groups

Baseline Measures

	Ranibizumab	Dexamethasone	Total
Number of Participants [units: participants]	**126**	**118**	**244**
Age [units: Years] Mean (Standard Deviation)	**65.7 (10.9)**	**65.6 (10.0)**	**65.6 (10.5)**
Gender [units: Participants]			
Female	**76**	**57**	**133**

Male	**50**	**61**	**111**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Average Best Corrected Visual Acuity (BCVA) Change From Month 1 Through Month 6 to Baseline [Time Frame: Baseline, month 6]

Measure Type	Primary
Measure Title	Mean Average Best Corrected Visual Acuity (BCVA) Change From Month 1 Through Month 6 to Baseline
Measure Description	the average of the changes in BCVA (letters) from baseline to any post-baseline visit, i.e. the mean of six differences to baseline for the six post-baseline visits at month 1 to 6
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**126**	**118**
Mean Average Best Corrected Visual Acuity (BCVA) Change From Month 1 Through Month 6 to Baseline [units: Letters] Mean (Standard Deviation)	**14.9 (9.9)**	**10.1 (9.5)**

No statistical analysis provided for Mean Average Best Corrected Visual Acuity (BCVA) Change From Month 1 Through Month 6 to Baseline

2. Secondary: Mean BCVA Change From Baseline to Endpoints Month 1 to Month 6 [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Mean BCVA Change From Baseline to Endpoints Month 1 to Month 6
Measure Description	The analysis was performed by an analysis of covariance (ANCOVA) model with average change in BCVA (letters) from Visit 1 through Visit 6 as dependent variable, and with the factors center, treatment and covariate baseline BCVA as predictors
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**126**	**118**
Mean BCVA Change From Baseline to Endpoints Month 1 to Month 6 [units: Letters (EDTRS)] Least Squares Mean (95% Confidence Interval)	**16.18 (14.04 to 18.32)**	**8.10 (5.79 to 10.40)**

No statistical analysis provided for Mean BCVA Change From Baseline to Endpoints Month 1 to Month 6

3. Secondary: Percentage of Patients Gaining / Losing ≥ 15 / 10 / 5 Letters After 6 Month Treatment [Time Frame: Baseline, 6 month]

Measure Type	Secondary
Measure Title	Percentage of Patients Gaining / Losing ≥ 15 / 10 / 5 Letters After 6 Month Treatment
Measure Description	BCVA score was based on the number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity chart assessed at a starting distance of 4 meters. An ETDRS visual acuity score of 85 is approximately 20/20. An increased score indicates improvement in acuity. This outcome assessed the percentage of participants who gained 15, 10 or 5 more letters of visual acuity at month 6 as compared with baseline
Time Frame	Baseline, 6 month
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**126**	**118**
Percentage of Patients Gaining / Losing ≥ 15 / 10 / 5 Letters After 6 Month Treatment [units: Participants]		
Gain≥15 letters	**77**	**44**
Loss of ≥15 letters	**0**	**6**
Gain ≥10 letters	**97**	**63**
Loss of ≥10 letters	**2**	**8**
Gain ≥5 letters	**108**	**76**
Loss of ≥5 letters	**4**	**14**

No statistical analysis provided for Percentage of Patients Gaining / Losing ≥ 15 / 10 / 5 Letters After 6 Month Treatment

4. Secondary: Time to Achieve a Significant Improvement ≥ 15 Letters [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Time to Achieve a Significant Improvement ≥ 15 Letters
Measure Description	The time was analyzed by the Kaplan-Maier-Method, adjusting the calculation for dropouts
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**126**	**118**
Time to Achieve a Significant Improvement ≥ 15 Letters [units: Time to event (Days)] Median (95% Confidence Interval)	**63 (56 to 84)**	**64 (59 to 126)**

No statistical analysis provided for Time to Achieve a Significant Improvement ≥ 15 Letters

5. Secondary: Change Over Time in BCVA [Time Frame: baseline, month 6]

Measure Type	Secondary
Measure Title	Change Over Time in BCVA
Measure Description	The analysis was performed by an analysis of covariance (ANCOVA) model with average change in BCVA (letters) from Visit 1 through Visit 6 as dependent variable, and with the factors center, treatment and covariate baseline BCVA as predictors
Time Frame	baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	**Dexamethasone**

Number of Participants Analyzed [units: participants]	**126**	**118**
Change Over Time in BCVA [units: Letters] Least Squares Mean (95% Confidence Interval)		
Month 1	**10.35 (8.53 to 12.17)**	**10.44 (8.48 to 12.40)**
Month 2	**13.84 (12.04 to 15.64)**	**12.62 (10.69 to 14.56)**
Month 3	**15.52 (13.44 to 17.59)**	**9.16 (6.92 to 11.39)**
Month 4	**14.39 (12.38 to 16.41)**	**8.59 (6.42 to 10.76)**
Month 5	**14.65 (12.52 to 16.78)**	**9.08 (6.79 to 11.37)**
Month 6	**16.18 (14.04 to 18.32)**	**8.10 (5.79 to 10.40)**

No statistical analysis provided for Change Over Time in BCVA

6. Secondary: Change Over Time of the Central Retinal Thickness (CRT) [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Change Over Time of the Central Retinal Thickness (CRT)
Measure Description	Retinal thickness was measured using Optical Coherence Tomography (OCT). The images were reviewed by a central reading center to ensure a standardized evaluation
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**126**	**118**
Change Over Time of the Central Retinal Thickness (CRT) [units: µm] Mean (Standard Deviation)	**-230.6 (169.3)**	**-112.3 (172.1)**

No statistical analysis provided for Change Over Time of the Central Retinal Thickness (CRT)

7. Secondary: Changes in the Quality of Life According to the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25) Questionnaires [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Changes in the Quality of Life According to the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25)

	Questionnaires
Measure Description	The VFQ-25 composite and subscale scores range from 0 to 100, a higher score indicating better functioning. The 12 subscales in the VFQ-25 are general health, general vision, ocular pain, near activities, distance activities, social function, mental health, role difficulties, dependency, driving, color vision, and peripheral vision. The scores on the subscales were added together for a total score, which ranged from 0 to 100. A higher score indicated improvement in quality of life due to vision function.
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**126**	**118**
Changes in the Quality of Life According to the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25) Questionnaires	**7.2 (10.2)**	**2.8 (12.6)**

[units: Score on a scale] **Mean (Standard Deviation)**		

No statistical analysis provided for Changes in the Quality of Life According to the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25) Questionnaires

8. Secondary: Changes in the Quality of Life According to the Short Form (36) Health Survey (SF-36)Questionnaires [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Changes in the Quality of Life According to the Short Form (36) Health Survey (SF-36)Questionnaires
Measure Description	SF-36 summary measures are norm-based scores with mean = 50 and SD = 10. Higher scores indicate better health
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. observed is only described in this analysis.

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**126**	**118**
Changes in the Quality of Life According to the Short Form (36) Health Survey (SF-36)Questionnaires [units: Units on a scale] Mean (Standard Deviation)		
SF-36 physical component (n=121,114)	**-1.1 (5.7)**	**-0.4 (5.7)**
SF-36 mental component (n=121,114)	**3.3 (9.2)**	**0.2 (9.6)**

No statistical analysis provided for Changes in the Quality of Life According to the Short Form (36) Health Survey (SF-36)Questionnaires

9. Secondary: Changes in the Quality of Life According to Euro Quality of Life (EQ-5D) Questionnaires [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Changes in the Quality of Life According to Euro Quality of Life (EQ-5D) Questionnaires
Measure Description	The EQ-5D visual analog scale ranges from 0 to 100, 0 representing the worst and 100 the best imaginable health state.
Time Frame	Baseline, month 6
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.
The Full Analysis Set (FAS) consisted of all patients from the Randomized Set (RS) who had received at least one application of study treatment and had at least one post-baseline assessment for BCVA. Observed participants are only described in this analysis

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**123**	**118**
Changes in the Quality of Life According to Euro Quality of Life (EQ-5D) Questionnaires [units: Units on a scale] Mean (Standard Deviation)	**0.7 (15.2)**	**-2.4 (15.4)**

No statistical analysis provided for Changes in the Quality of Life According to Euro Quality of Life (EQ-5D) Questionnaires

10. Secondary: Rate of the Internal Ocular Pressure (IOP) [Time Frame: Baseline, month 6]

Measure Type	Secondary
Measure Title	Rate of the Internal Ocular Pressure (IOP)
Measure Description	The proportion of patients with ≥ 10% increase in IOP compared to baseline at any post-baseline visit.
Time Frame	Baseline, month 6
Safety Issue	Yes

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.
The Safety Set consisted of all patients from the RS who had received at least one application of study treatment and had at least one post-baseline safety assessment. Patients were analyzed according to treatment received. The statement that a patient had no adverse events

also constituted a safety assessment

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Measured Values

	Ranibizumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**126**	**118**
Rate of the Internal Ocular Pressure (IOP) [units: Participants]	**79**	**106**

No statistical analysis provided for Rate of the Internal Ocular Pressure (IOP)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Serious Adverse Events

	Ranibizumab	Dexamethasone
Total, serious adverse events		
# participants affected / at risk	**7/126 (5.56%)**	**9/118 (7.63%)**
Cardiac disorders		
ATRIOVENTRICULAR BLOCK SECOND DEGREE † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**0/118 (0.00%)**
BRADYARRHYTHMIA † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**0/118 (0.00%)**
Eye disorders		
CONJUNCTIVITIS (Study eye) † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
OCULAR HYPERTENSION (Study eye) † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
Gastrointestinal disorders		
ABDOMINAL HERNIA † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
CONSTIPATION † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**0/118 (0.00%)**
DYSPEPSIA † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**0/118 (0.00%)**
INGUINAL HERNIA † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
LARGE INTESTINE POLYP † [1]		

# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
RECTAL HAEMORRHAGE † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
UMBILICAL HERNIA † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
General disorders		
FATIGUE † [1]		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
Infections and infestations		
APPENDICITIS † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
BRONCHITIS † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
CELLULITIS (Study eye) † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
Injury, poisoning and procedural complications		
FOOT FRACTURE † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
KIDNEY RUPTURE † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
PERIRENAL HAEMATOMA † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
ROAD TRAFFIC ACCIDENT † [1]		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
SPLENIC INJURY † [1]		

# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
Metabolism and nutrition disorders		
TYPE 2 DIABETES MELLITUS † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
Musculoskeletal and connective tissue disorders		
INTERVERTEBRAL DISC PROTRUSION † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
RHEUMATIC DISORDER † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
PROSTATE CANCER † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
RENAL CANCER † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
Renal and urinary disorders		
DIABETIC NEPHROPATHY † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
NEPHROLITHIASIS † 1		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
RENAL FAILURE † 1		
# participants affected / at risk	1/126 (0.79%)	0/118 (0.00%)
URETHRAL PROLAPSE † 1		
# participants affected / at risk	0/126 (0.00%)	1/118 (0.85%)
Respiratory, thoracic and mediastinal disorders		
PULMONARY EMBOLISM † 1		

# participants affected / at risk	**1/126 (0.79%)**	**0/118 (0.00%)**
SLEEP APNOEA SYNDROME † 1		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
Vascular disorders		
CIRCULATORY COLLAPSE † 1		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**
HYPERTENSION † 1		
# participants affected / at risk	**0/126 (0.00%)**	**1/118 (0.85%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	2.5%

Reporting Groups

	Description
Ranibizumab	Injections consisted of 0.5 mg/0.05 ml solution to be injected intravitreally
Dexamethasone	Intravitreal implant as per commercial label (700 µg Dexamethasone; long acting release (LAR) over 6 months

Other Adverse Events

	Ranibizumab	Dexamethasone
Total, other (not including serious) adverse events		
# participants affected / at risk	**71/126 (56.35%)**	**89/118 (75.42%)**
Eye disorders		
ABNORMAL SENSATION IN EYE (Study eye) † [1]		
# participants affected / at risk	**5/126 (3.97%)**	**3/118 (2.54%)**
BLEPHARITIS (Fellow eye) † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**3/118 (2.54%)**
BLEPHARITIS (Study eye) † [1]		
# participants affected / at risk	**2/126 (1.59%)**	**5/118 (4.24%)**
CATARACT (Study eye) † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**4/118 (3.39%)**
CONJUNCTIVAL HAEMORRHAGE (Study eye) † [1]		
# participants affected / at risk	**12/126 (9.52%)**	**14/118 (11.86%)**
CONJUNCTIVAL IRRITATION (Study eye) † [1]		
# participants affected / at risk	**4/126 (3.17%)**	**4/118 (3.39%)**
CONJUNCTIVITIS (Study eye) † [1]		
# participants affected / at risk	**4/126 (3.17%)**	**2/118 (1.69%)**
EYE DISCHARGE (Study eye) † [1]		
# participants affected / at risk	**5/126 (3.97%)**	**5/118 (4.24%)**
EYE IRRITATION (Fellow eye) † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**3/118 (2.54%)**
EYE IRRITATION (Study eye) † [1]		
# participants affected / at risk	**3/126 (2.38%)**	**6/118 (5.08%)**
EYE PAIN (Study eye) † [1]		

# participants affected / at risk	**9/126 (7.14%)**	**13/118 (11.02%)**
EYELID OEDEMA (Study eye) † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**3/118 (2.54%)**
FOREIGN BODY SENSATION IN EYES (Study eye) † [1]		
# participants affected / at risk	**8/126 (6.35%)**	**4/118 (3.39%)**
GLAUCOMA (Study eye) † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**3/118 (2.54%)**
LACRIMATION INCREASED (Fellow eye) † [1]		
# participants affected / at risk	**2/126 (1.59%)**	**4/118 (3.39%)**
LACRIMATION INCREASED (Study eye) † [1]		
# participants affected / at risk	**7/126 (5.56%)**	**4/118 (3.39%)**
MACULAR OEDEMA (Study eye) † [1]		
# participants affected / at risk	**4/126 (3.17%)**	**7/118 (5.93%)**
OCULAR DISCOMFORT (Study eye) † [1]		
# participants affected / at risk	**2/126 (1.59%)**	**8/118 (6.78%)**
OCULAR HYPERAEMIA (Study eye) † [1]		
# participants affected / at risk	**16/126 (12.70%)**	**21/118 (17.80%)**
OCULAR HYPERTENSION (Study eye) † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**6/118 (5.08%)**
RETINAL EXUDATES (Study eye) † [1]		
# participants affected / at risk	**7/126 (5.56%)**	**3/118 (2.54%)**
VISION BLURRED (Study eye) † [1]		
# participants affected / at risk	**6/126 (4.76%)**	**2/118 (1.69%)**
VISUAL ACUITY REDUCED (Study eye) † [1]		
# participants affected / at risk	**4/126 (3.17%)**	**6/118 (5.08%)**

VITREOUS DETACHMENT (Study eye) † [1]		
# participants affected / at risk	**3/126 (2.38%)**	**7/118 (5.93%)**
VITREOUS FLOATERS (Study eye) † [1]		
# participants affected / at risk	**3/126 (2.38%)**	**3/118 (2.54%)**
Gastrointestinal disorders		
VOMITING † [1]		
# participants affected / at risk	**0/126 (0.00%)**	**3/118 (2.54%)**
Infections and infestations		
CYSTITIS † [1]		
# participants affected / at risk	**4/126 (3.17%)**	**1/118 (0.85%)**
LOWER RESPIRATORY TRACT INFECTION † [1]		
# participants affected / at risk	**3/126 (2.38%)**	**4/118 (3.39%)**
NASOPHARYNGITIS † [1]		
# participants affected / at risk	**20/126 (15.87%)**	**21/118 (17.80%)**
Injury, poisoning and procedural complications		
FALL † [1]		
# participants affected / at risk	**6/126 (4.76%)**	**3/118 (2.54%)**
Investigations		
BLOOD GLUCOSE INCREASED † [1]		
# participants affected / at risk	**1/126 (0.79%)**	**4/118 (3.39%)**
INTRAOCULAR PRESSURE INCREASED † [1]		
# participants affected / at risk	**3/126 (2.38%)**	**19/118 (16.10%)**
INTRAOCULAR PRESSURE INCREASED (Study eye) † [1]		
# participants affected / at risk	**2/126 (1.59%)**	**17/118 (14.41%)**
Musculoskeletal and connective tissue disorders		

BACK PAIN † 1		
# participants affected / at risk	**5/126 (3.97%)**	**6/118 (5.08%)**
PAIN IN EXTREMITY † 1		
# participants affected / at risk	**5/126 (3.97%)**	**1/118 (0.85%)**
Nervous system disorders		
HEADACHE † 1		
# participants affected / at risk	**13/126 (10.32%)**	**11/118 (9.32%)**
Respiratory, thoracic and mediastinal disorders		
OROPHARYNGEAL PAIN † 1		
# participants affected / at risk	**6/126 (4.76%)**	**3/118 (2.54%)**
Vascular disorders		
HYPERTENSION † 1		
# participants affected / at risk	**7/126 (5.56%)**	**5/118 (4.24%)**
VASCULAR SHUNT (Study eye) † 1		
# participants affected / at risk	**4/126 (3.17%)**	**0/118 (0.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

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: ☐ 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. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300
e-mail: trialandresults.registries@novartis.com

No publications provided

Responsible Party: Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT01396057 History of Changes

Other Study ID Numbers:	**CRFB002EDE17** 2011-001019-30 (EudraCT Number)
Study First Received:	July 14, 2011
Results First Received:	June 13, 2014
Last Updated:	August 4, 2014
Health Authority:	Germany: Paul-Ehrlich-Institut