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Trial record **1 of 1** for: CRFB002D2201
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Safety and Efficacy of Ranibizumab in Diabetic Macular Edema With Center Involvement (RESOLVE)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00284050

First received: January 30, 2006
Last updated: February 22, 2011
Last verified: February 2011
History of Changes

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

Results First Received: December 20, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Diabetic Macular Edema
Interventions:	Drug: Ranibizumab 0.3 mg Drug: Ranibizumab 0.5 mg Drug: 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 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Participant Flow: Overall Study

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection
STARTED	51	51	49
COMPLETED	46	46	40
NOT COMPLETED	5	5	9
Adverse Event	1	1	1
Lack of Efficacy	0	1	3
Protocol Violation	0	1	2
Withdrawal by Subject	2	2	2
Lost to Follow-up	1	0	1
Death	1	0	0

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 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted

	with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Total	Total of all reporting groups

Baseline Measures

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection	Total
Number of Participants [units: participants]	51	51	49	151
Age [units: years] Mean (Standard Deviation)	63.2 (10.44)	62.8 (10.14)	65.0 (9.26)	63.6 (9.95)
Gender [units: participants]				
Female	22	24	24	70
Male	29	27	25	81

Outcome Measures

Hide All Outcome Measures

1. Primary: Difference Between the Baseline Level of Visual Acuity (Letters) of the Study Eye and the Mean Visual Acuity Averaged Over All Monthly Post-baseline Assessments From Month 1 to Month 12 [Time Frame: Baseline through the end of study (Month 12)]

Measure Type	Primary
Measure Title	Difference Between the Baseline Level of Visual Acuity (Letters) of the Study Eye and the Mean Visual Acuity Averaged Over All Monthly Post-baseline Assessments From Month 1 to Month 12
Measure Description	Visual acuity (VA) was assessed on both eyes during every study visit using best correction determined from protocol refraction. VA measurements were performed with the patient in a sitting position using Early Treatment Diabetic Retinopathy Study (ETDRS)-like visual acuity testing charts at a testing distance of 4 meters as described in the Study Operations Manual.
Time Frame	Baseline through the end of study (Month 12)
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.
Full Analysis Set (FAS): All patients who received at least one application of study treatment and had at least one post-baseline assessment for BCVA. A Last Observation Carried Forward (LOCF) approach was used; missing values were replaced by the mean of the last observation before and the first observation after the missing time-point.

Reporting Groups

	Description
Ranibizumab 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg

	was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Measured Values

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection
Number of Participants Analyzed [units: participants]	51	51	49
Difference Between the Baseline Level of Visual Acuity (Letters) of the Study Eye and the Mean Visual Acuity Averaged Over All Monthly Post-baseline Assessments From Month 1 to Month 12 [units: Letters] Mean (Standard Deviation)	9.2 (5.60)	6.4 (9.21)	-0.1 (9.77)

No statistical analysis provided for Difference Between the Baseline Level of Visual Acuity (Letters) of the Study Eye and the Mean Visual Acuity Averaged Over All Monthly Post-baseline Assessments From Month 1 to Month 12

2. Primary: Mean Change From Baseline in Visual Acuity (Letters) of the Study Eye at Month 12 [Time Frame: Baseline through the end of study (Month 12)]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Visual Acuity (Letters) of the Study Eye at Month 12
Measure Description	Visual acuity (VA) was assessed on both eyes during every study visit using best correction determined from protocol refraction. VA measurements were performed with the patient in a sitting position using Early Treatment Diabetic

	Retinopathy Study (ETDRS)-like visual acuity testing charts at a testing distance of 4 meters as described in the Study Operations Manual.
Time Frame	Baseline through the end of study (Month 12)
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.
Full Analysis Set (FAS): All patients who received at least one application of study treatment and had at least one post-baseline assessment for BCVA. A Last Observation Carried Forward (LOCF) approach was used; missing values were replaced by the mean of the last observation before and the first observation after the missing time-point.

Reporting Groups

	Description
Ranibizumab 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Measured Values

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection
Number of Participants Analyzed [units: participants]	51	51	49
Mean Change From Baseline in Visual Acuity (Letters) of the Study Eye at Month 12 [units: Letters] Mean (Standard Deviation)	11.8 (6.59)	8.8 (10.99)	-1.4 (14.16)

No statistical analysis provided for Mean Change From Baseline in Visual Acuity (Letters) of the Study Eye at Month 12

3. Secondary: Mean Change From Baseline in Central Retinal Thickness (μm) of the Study Eye at Month 12 [Time Frame: Baseline through the end of study (Month 12)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Central Retinal Thickness (μm) of the Study Eye at Month 12
Measure Description	Optical Coherence Tomography (OCT) was assessed on both eyes at every study visit. These assessments were performed by trained personnel at the sites. OCT imaging was performed using the Zeiss Humphrey System Model 2000 (or later) with version A6.1 software running under Windows 95 or Windows 98. The analysis of the OCT images were performed by the Photographic Reading Center which provided a study manual and training materials. OCT operators, systems and software were certified prior to any evaluation of study patients.
Time Frame	Baseline through the end of study (Month 12)
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.

Full Analysis Set (FAS): All patients who received at least one application of study treatment and had at least one post-baseline assessment for BCVA. A Last Observation Carried Forward (LOCF) approach was used; missing values were replaced by the mean of the last observation before and the first observation after the missing time-point.

Reporting Groups

	Description
Ranibizumab 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Measured Values

	Ranibizumab 0.3 mg	**Ranibizumab 0.5 mg**	**Sham Injection**
Number of Participants Analyzed **[units: participants]**	**51**	**51**	**49**
Mean Change From Baseline in Central Retinal Thickness (µm) of the Study Eye at Month 12 **[units: µm]** **Mean (Standard Deviation)**	**-200.7 (122.18)**	**-187.6 (147.82)**	**-48.4 (153.43)**

No statistical analysis provided for Mean Change From Baseline in Central Retinal Thickness (µm) of the Study Eye at Month 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Ranibizumab 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
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Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Serious Adverse Events

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection
Total, serious adverse events			
# participants affected / at risk	9/51 (17.65%)	9/51 (17.65%)	9/49 (18.37%)
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Cardiac disorders			
Angina pectoris † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Myocardial infarction † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	1/49 (2.04%)
Eye disorders			
Endophthalmitis (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	1/51 (1.96%)	0/49 (0.00%)
Retinal artery occlusion (Study eye) † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	0/49 (0.00%)
Retinal detachment (Study eye) † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Retinal ischaemia (Study eye) † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	0/49 (0.00%)
Vitreous haemorrhage (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
General disorders			
Pitting oedema † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)

Infections and infestations			
Cellulitis † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Diabetic gangrene † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Gastroenteritis † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Gastroenteritis viral † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Infected epidermal cyst † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	0/49 (0.00%)
Injury, poisoning and procedural complications			
Allergic transfusion reaction † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Concussion † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Radius fracture † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Spinal fracture † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Metabolism and nutrition disorders			
Diabetes mellitus inadequate control † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Hyperglycaemia † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)

Hypoglycaemia † [1]			
# participants affected / at risk	1/51 (1.96%)	1/51 (1.96%)	0/49 (0.00%)
Musculoskeletal and connective tissue disorders			
Back pain † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Intervertebral disc protrusion † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Osteoarthritis † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Lung neoplasm malignant † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	0/49 (0.00%)
Nervous system disorders			
Transient ischaemic attack † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	0/49 (0.00%)
Renal and urinary disorders			
Nephrolithiasis † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	0/49 (0.00%)
Renal failure † [1]			
# participants affected / at risk	0/51 (0.00%)	0/51 (0.00%)	1/49 (2.04%)
Renal failure chronic † [1]			
# participants affected / at risk	0/51 (0.00%)	1/51 (1.96%)	1/49 (2.04%)

Respiratory, thoracic and mediastinal disorders			
Dyspnoea † 1			
# participants affected / at risk	**0/51 (0.00%)**	**0/51 (0.00%)**	**1/49 (2.04%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**0/51 (0.00%)**	**0/51 (0.00%)**	**1/49 (2.04%)**

† 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	5%

Reporting Groups

	Description
Ranibizumab 0.3 mg	Participants received monthly intravitreal injections with 0.3 mg ranibizumab (6 mg/ml) for up to 12 months. At each monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 0.6 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Ranibizumab 0.5 mg	Participants received monthly intravitreal injections with 0.5 mg ranibizumab (10 mg/ml) for up to 12 months. At each

	monthly visit from month 1 and onwards, the evaluating physician decided whether an increase in the dose to 1.0 mg was needed according to set criteria. If the dose was increased, all subsequent administrations were of the higher dose unless treatment had been withheld for more than 45 days (for any reason), in which case injections restarted with the initial dose. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.
Sham Injection	Participants in the control group received 12 monthly sham intravitreal injections. The evaluation was performed using the same criteria for dose doubling as in active treatment groups. The injection was a mimicked by an empty syringe without a needle. Laser photocoagulation was permitted as rescue treatment for the study eye after 3 consecutive monthly injections.

Other Adverse Events

	Ranibizumab 0.3 mg	Ranibizumab 0.5 mg	Sham Injection
Total, other (not including serious) adverse events			
# participants affected / at risk	37/51 (72.55%)	43/51 (84.31%)	32/49 (65.31%)
Eye disorders			
Cataract (Fellow eye) † [1]			
# participants affected / at risk	0/51 (0.00%)	4/51 (7.84%)	2/49 (4.08%)
Conjunctival haemorrhage (Study eye) † [1]			
# participants affected / at risk	10/51 (19.61%)	13/51 (25.49%)	7/49 (14.29%)
Conjunctival hyperaemia (Study eye) † [1]			
# participants affected / at risk	2/51 (3.92%)	1/51 (1.96%)	3/49 (6.12%)
Conjunctivitis (Fellow eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	4/49 (8.16%)
Conjunctivitis (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	1/51 (1.96%)	4/49 (8.16%)
Corneal disorder (Study eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	2/51 (3.92%)	0/49 (0.00%)
Eye irritation (Study eye) † [1]			

# participants affected / at risk	3/51 (5.88%)	1/51 (1.96%)	1/49 (2.04%)
Eye pain (Study eye) † [1]			
# participants affected / at risk	9/51 (17.65%)	9/51 (17.65%)	10/49 (20.41%)
Eye pruritus (Study eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	2/51 (3.92%)	2/49 (4.08%)
Eyelid oedema (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	0/51 (0.00%)	3/49 (6.12%)
Foreign body sensation in eyes (Study eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	3/51 (5.88%)	1/49 (2.04%)
Lacrimation increased (Study eye) † [1]			
# participants affected / at risk	4/51 (7.84%)	4/51 (7.84%)	0/49 (0.00%)
Macular oedema (Fellow eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	2/51 (3.92%)	0/49 (0.00%)
Ocular hyperaemia (Study eye) † [1]			
# participants affected / at risk	2/51 (3.92%)	2/51 (3.92%)	4/49 (8.16%)
Retinal disorder (Study eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	1/51 (1.96%)	0/49 (0.00%)
Retinal exudates (Study eye) † [1]			
# participants affected / at risk	2/51 (3.92%)	1/51 (1.96%)	4/49 (8.16%)
Retinal haemorrhage (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	2/51 (3.92%)	3/49 (6.12%)
Visual acuity reduced (Study eye) † [1]			
# participants affected / at risk	1/51 (1.96%)	6/51 (11.76%)	5/49 (10.20%)
Visual disturbance (Study eye) † [1]			
# participants affected / at risk	3/51 (5.88%)	1/51 (1.96%)	1/49 (2.04%)

Vitreous floaters (Study eye) † [1]			
# participants affected / at risk	**1/51 (1.96%)**	**8/51 (15.69%)**	**0/49 (0.00%)**
Vitreous haemorrhage (Fellow eye) † [1]			
# participants affected / at risk	**3/51 (5.88%)**	**4/51 (7.84%)**	**3/49 (6.12%)**
Vitreous haemorrhage (Study eye) † [1]			
# participants affected / at risk	**0/51 (0.00%)**	**4/51 (7.84%)**	**0/49 (0.00%)**
Gastrointestinal disorders			
Nausea † [1]			
# participants affected / at risk	**1/51 (1.96%)**	**1/51 (1.96%)**	**3/49 (6.12%)**
Infections and infestations			
Bronchitis † [1]			
# participants affected / at risk	**1/51 (1.96%)**	**3/51 (5.88%)**	**2/49 (4.08%)**
Influenza † [1]			
# participants affected / at risk	**2/51 (3.92%)**	**3/51 (5.88%)**	**1/49 (2.04%)**
Nasopharyngitis † [1]			
# participants affected / at risk	**5/51 (9.80%)**	**5/51 (9.80%)**	**1/49 (2.04%)**
Investigations			
Intraocular pressure increased (Fellow eye) † [1]			
# participants affected / at risk	**1/51 (1.96%)**	**3/51 (5.88%)**	**0/49 (0.00%)**
Intraocular pressure increased (Study eye) † [1]			
# participants affected / at risk	**6/51 (11.76%)**	**15/51 (29.41%)**	**1/49 (2.04%)**
Respiratory, thoracic and mediastinal disorders			
Cough † [1]			
# participants affected / at risk	**1/51 (1.96%)**	**3/51 (5.88%)**	**2/49 (4.08%)**
Vascular disorders			

Hypertension † 1			
# participants affected / at risk	**3/51 (5.88%)**	**4/51 (7.84%)**	**3/49 (6.12%)**

† 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.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862 778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Massin P, Bandello F, Garweg JG, Hansen LL, Harding SP, Larsen M, Mitchell P, Sharp D, Wolf-Schnurrbusch UE, Gekkieva M, Weichselberger A, Wolf S. Safety and efficacy of ranibizumab in diabetic macular edema (RESOLVE Study): a 12-month, randomized, controlled, double-masked, multicenter phase II study. Diabetes Care. 2010 Nov;33(11):2399-405. doi: 10.2337/dc10-0493.

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00284050 History of Changes
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