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Trial record **2 of 2** for: CRFB002A2302

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Efficacy and Safety of Ranibizumab in Patients With Subfoveal Choroidal Neovascularization (CNV) Secondary to Age-related Macular Degeneration (AMD) (EXCITE)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00275821

First received: January 11, 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 (Subject, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Age Related Macular Degeneration
Interventions:	Drug: Ranibizumab 0.3 mg - 3 times monthly, then quarterly Drug: Ranibizumab 0.5 mg - 3 times monthly, then quarterly Drug: Ranibizumab 0.3 mg monthly

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 - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Participant Flow: Overall Study

	Ranibizumab 0.3 mg - 3 Times Monthly,	Ranibizumab 0.5 mg - 3 Times Monthly,	Ranibizumab 0.3 mg

	Then Quarterly	Then Quarterly	Monthly
STARTED	**120**	**118**	**115**
COMPLETED	**106**	**95**	**103**
NOT COMPLETED	**14**	**23**	**12**
Adverse Event	**4**	**12**	**5**
Administrative problems	**3**	**4**	**4**
Withdrawal by Subject	**0**	**2**	**1**
Lost to Follow-up	**0**	**1**	**1**
Death	**0**	**2**	**1**
Lack of Efficacy	**2**	**1**	**0**
Protocol Violation	**5**	**1**	**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 - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg

	over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Total	Total of all reporting groups

Baseline Measures

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.3 mg Monthly	Total
Number of Participants [units: participants]	**120**	**118**	**115**	**353**
Age, Customized [units: Participants]				
50 - < 65	**13**	**12**	**10**	**35**
65 - < 75	**37**	**28**	**45**	**110**
75 - < 85	**61**	**72**	**46**	**179**
≥ 85	**9**	**6**	**14**	**29**

Gender [units: participants]				
Female	70	73	66	209
Male	50	45	49	144

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Best-corrected Visual Acuity of the Study Eye at Month 12 [Time Frame: Baseline to Month 12]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Best-corrected Visual Acuity of the Study Eye at Month 12
Measure Description	Visual acuity (VA) was assessed in both eyes at each study visit using best correction determined from protocol refraction. VA measurements were taken in a sitting position using Early Treatment Diabetic Retinopathy Study (ETDRS)-like visual acuity testing charts at an initial testing distance of 4 meters.
Time Frame	Baseline to 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.
Per-Protocol (PP) population includes a subset of patients from the Intent to Treat (ITT) population who completed Month 12/Visit 15, had an assessment of Best Corrected Visual Acuity in the study eye at Month 12/Visit 15 and did not have any major study protocol deviations.

Reporting Groups

	Description

Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Measured Values

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	**Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly**	**Ranibizumab 0.3 mg Monthly**
Number of Participants Analyzed [units: participants]	**104**	**88**	**101**
Mean Change From Baseline in Best-corrected Visual Acuity of the Study Eye at Month 12 [units: letters] Mean (Standard Deviation)	**4.9 (13.13)**	**3.8 (13.33)**	**8.3 (11.31)**

No statistical analysis provided for Mean Change From Baseline in Best-corrected Visual Acuity of the Study Eye at Month 12

2. Secondary: Mean Change From Baseline in the Total Lesion Area of the Study Eye at Month 12 [Time Frame: Baseline to Month 12]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in the Total Lesion Area of the Study Eye at Month 12
Measure Description	Fluorescein angiography was conducted in conjunction with color fundus photography at screening and at Months 6 and 12. Investigators used digital fluorescein angiograms to determine presence or absence of choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).
Time Frame	Baseline to 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.
The intent to treat (ITT) population, with use of Last Observation Carried Forward (LOCF), consisted of all patients randomized into the study. Patients were analyzed according to the treatment group to which they were randomized. Only patients with available data at baseline and Month 12 were included in the analysis.

Reporting Groups

	Description
Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Measured Values

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.3 mg Monthly
Number of Participants Analyzed [units: participants]	**113**	**105**	**108**
Mean Change From Baseline in the Total Lesion Area of the Study Eye at Month 12 [units: mm^2] Mean (Standard Deviation)	**-0.21 (5.616)**	**-1.51 (4.802)**	**-1.28 (4.367)**

No statistical analysis provided for Mean Change From Baseline in the Total Lesion Area of the Study Eye at Month 12

3. Secondary: Mean Change From Baseline in Retinal Thickness at the Central Point of the Study Eye at Month 12 [Time Frame: Baseline to Month 12]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Retinal Thickness at the Central Point of the Study Eye at Month 12
Measure Description	Optical Coherence Tomography (OCT) was performed on both eyes at screening and monthly from baseline through Month 12 prior to study drug administration. OCT images were evaluated at the central reading center (CRC) by trained graders and ophthalmologists experienced in clinical trials.
Time Frame	Baseline to 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.
Intent to Treat (ITT) population, with use of Last Observation Carried Forward (LOCF), consisted of all patients randomized into the study. Patients were analyzed according to the treatment group to which they were randomized. Only patients with available data at baseline and

Month 12 were included in the analysis.

Reporting Groups

	Description
Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Measured Values

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.3 mg Monthly
Number of Participants Analyzed [units: participants]	**100**	**100**	**95**
Mean Change From Baseline in Retinal Thickness at the Central Point of the Study Eye at Month 12 [units: micrometers] Mean (Standard Deviation)	**-96.0 (96.82)**	**-105.6 (128.98)**	**-105.3 (128.55)**

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

4. Secondary: Mean Change From Baseline in Retinal Thickness at the Central Subfield of the Study Eye at Month 12 [Time Frame: Baseline to Month 12]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Retinal Thickness at the Central Subfield of the Study Eye at Month 12
Measure Description	Optical Coherence Tomography (OCT) was performed on both eyes at screening and monthly from baseline through Month 12 prior to study drug administration. OCT images were evaluated at the central reading center (CRC) by trained graders and ophthalmologists experienced in clinical trials.
Time Frame	Baseline to 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.
Intent to Treat (ITT) population, with use of Last Observation Carried Forward (LOCF), consisted of all patients randomized into the study. Patients were analyzed according to the treatment group to which they were randomized. Only patients with available data at baseline and Month 12 were included in the analysis.

Reporting Groups

	Description
Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when

	ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Measured Values

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.3 mg Monthly
Number of Participants Analyzed [units: participants]	**100**	**100**	**95**
Mean Change From Baseline in Retinal Thickness at the Central Subfield of the Study Eye at Month 12 [units: Micrometers] Mean (Standard Deviation)	**-93.3 (100.88)**	**-97.5 (117.52)**	**-97.9 (112.47)**

No statistical analysis provided for Mean Change From Baseline in Retinal Thickness at the Central Subfield 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 - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
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Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Serious Adverse Events

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Ranibizumab 0.3 mg Monthly
Total, serious adverse events			
# participants affected / at risk	**15/120 (12.50%)**	**23/118 (19.49%)**	**20/115 (17.39%)**
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Cardiac disorders			
Angina pectoris † [1]			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Arrhythmia † [1]			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Atrial fibrillation † [1]			

# participants affected / at risk	0/120 (0.00%)	2/118 (1.69%)	2/115 (1.74%)
Atrial flutter † [1]			
# participants affected / at risk	0/120 (0.00%)	2/118 (1.69%)	0/115 (0.00%)
Atrial tachycardia † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Cardiac failure † [1]			
# participants affected / at risk	3/120 (2.50%)	0/118 (0.00%)	1/115 (0.87%)
Cardio-respiratory arrest † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Myocardial infarction † [1]			
# participants affected / at risk	1/120 (0.83%)	0/118 (0.00%)	1/115 (0.87%)
Palpitations † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Ventricular tachycardia † [1]			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Ear and labyrinth disorders			
Vertigo † [1]			
# participants affected / at risk	1/120 (0.83%)	0/118 (0.00%)	0/115 (0.00%)
Eye disorders			
Blindness transient (Study eye) † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Choroidal neovascularisation (Fellow eye) † [1]			
# participants affected / at risk	1/120 (0.83%)	0/118 (0.00%)	0/115 (0.00%)
Retinal artery spasm (Study eye) † [1]			
# participants affected / at risk	1/120 (0.83%)	0/118 (0.00%)	0/115 (0.00%)

Retinal detachment (Study eye) † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Retinal haemorrhage (Study eye) † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Retinal pigment epithelial tear (Study eye) † 1			
# participants affected / at risk	**0/120 (0.00%)**	**2/118 (1.69%)**	**0/115 (0.00%)**
Visual acuity reduced (Study eye) † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Dysphagia † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Gastric ulcer † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Inguinal hernia † 1			
# participants affected / at risk	**1/120 (0.83%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Pancreatic cyst † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Rectal haemorrhage † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Vomiting † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
General disorders			
Pyrexia † 1			

# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Hepatobiliary disorders			
Biliary colic † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Cholelithiasis † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Infections and infestations			
Appendicitis † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Device related infection † [1]			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Gastroenteritis † [1]			
# participants affected / at risk	1/120 (0.83%)	1/118 (0.85%)	0/115 (0.00%)
Influenza † [1]			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Lung infection † [1]			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Perianal abscess † [1]			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Pneumonia † [1]			
# participants affected / at risk	1/120 (0.83%)	0/118 (0.00%)	2/115 (1.74%)
Sepsis † [1]			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Injury, poisoning and procedural complications			

Cataract traumatic (Study eye) † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Femoral neck fracture † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Femur fracture † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Lower limb fracture † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Rib fracture † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Metabolism and nutrition disorders			
Dehydration † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Musculoskeletal and connective tissue disorders			
Arthritis † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Osteoarthritis † 1			
# participants affected / at risk	**1/120 (0.83%)**	**1/118 (0.85%)**	**1/115 (0.87%)**
Rotator cuff syndrome † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma (Study eye) † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Bladder cancer † 1			

# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Breast cancer recurrent † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Metastases to bone † 1			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Ovarian cancer † 1			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Prostate cancer † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Rectosigmoid cancer † 1			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Transitional cell carcinoma † 1			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Nervous system disorders			
Cerebral haemorrhage † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Cerebrovascular accident † 1			
# participants affected / at risk	0/120 (0.00%)	0/118 (0.00%)	1/115 (0.87%)
Dementia † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	1/115 (0.87%)
Headache † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Ischaemic cerebral infarction † 1			
# participants affected / at risk	0/120 (0.00%)	1/118 (0.85%)	0/115 (0.00%)
Syncope † 1			

# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Syncope vasovagal † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Vertebrobasilar insufficiency † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Dyspnoea † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Pleural effusion † 1			
# participants affected / at risk	**0/120 (0.00%)**	**1/118 (0.85%)**	**0/115 (0.00%)**
Pulmonary embolism † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Pulmonary oedema † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**
Surgical and medical procedures			
Removal of internal fixation † 1			
# participants affected / at risk	**1/120 (0.83%)**	**0/118 (0.00%)**	**0/115 (0.00%)**
Vascular disorders			
Venous thrombosis † 1			
# participants affected / at risk	**0/120 (0.00%)**	**0/118 (0.00%)**	**1/115 (0.87%)**

† 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 - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.3 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly	Subjects received intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. They were treated monthly for 3 consecutive months and then quarterly for the remainder of the study. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.
Ranibizumab 0.3 mg Monthly	Subjects received monthly intravitreal injections (in the study eye) of ranibizumab 0.5 mg over a duration of 12 months. On those months when ranibizumab was not administered, patients received a sham injection to preserve the masking of the treatment arms.

Other Adverse Events

	Ranibizumab 0.3 mg - 3 Times Monthly, Then Quarterly	**Ranibizumab 0.5 mg - 3 Times Monthly, Then Quarterly**	**Ranibizumab 0.3 mg Monthly**

Total, other (not including serious) adverse events			
# participants affected / at risk	**66/120 (55.00%)**	**71/118 (60.17%)**	**64/115 (55.65%)**
Eye disorders			
Blepharitis (Study eye) † [1]			
# participants affected / at risk	**3/120 (2.50%)**	**6/118 (5.08%)**	**3/115 (2.61%)**
Choroidal neovascularisation (Fellow eye) † [1]			
# participants affected / at risk	**7/120 (5.83%)**	**6/118 (5.08%)**	**3/115 (2.61%)**
Conjunctival haemorrhage (Study eye) † [1]			
# participants affected / at risk	**23/120 (19.17%)**	**19/118 (16.10%)**	**12/115 (10.43%)**
Eye pain (Study eye) † [1]			
# participants affected / at risk	**22/120 (18.33%)**	**14/118 (11.86%)**	**24/115 (20.87%)**
Eye pruritus (Study eye) † [1]			
# participants affected / at risk	**1/120 (0.83%)**	**3/118 (2.54%)**	**6/115 (5.22%)**
Lacrimation increased (Study eye) † [1]			
# participants affected / at risk	**4/120 (3.33%)**	**1/118 (0.85%)**	**6/115 (5.22%)**
Ocular hyperaemia (Study eye) † [1]			
# participants affected / at risk	**8/120 (6.67%)**	**10/118 (8.47%)**	**7/115 (6.09%)**

Retinal haemorrhage (Study eye) † [1]			
# participants affected / at risk	**4/120 (3.33%)**	**8/118 (6.78%)**	**2/115 (1.74%)**
Visual acuity reduced (Study eye) † [1]			
# participants affected / at risk	**15/120 (12.50%)**	**19/118 (16.10%)**	**9/115 (7.83%)**
Vitreous floaters (Study eye) † [1]			
# participants affected / at risk	**6/120 (5.00%)**	**6/118 (5.08%)**	**8/115 (6.96%)**
Infections and infestations			
Nasopharyngitis † [1]			
# participants affected / at risk	**11/120 (9.17%)**	**4/118 (3.39%)**	**8/115 (6.96%)**
Investigations			
Intraocular pressure increased (Study eye) † [1]			
# participants affected / at risk	**6/120 (5.00%)**	**7/118 (5.93%)**	**17/115 (14.78%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † [1]			
# participants affected / at risk	**1/120 (0.83%)**	**3/118 (2.54%)**	**7/115 (6.09%)**
Nervous system disorders			
Headache † [1]			
# participants affected / at risk	**2/120 (1.67%)**	**6/118 (5.08%)**	**5/115 (4.35%)**

Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**10/120 (8.33%)**	**6/118 (5.08%)**	**8/115 (6.96%)**

† 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

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00275821 History of Changes
Other Study ID Numbers:	**CRFB002A2302**
Study First Received:	January 11, 2006
Results First Received:	December 20, 2010
Last Updated:	February 22, 2011
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP