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Trial record **2 of 2** for: CRFB002A2303

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SUSTAIN - Study of Ranibizumab in Patients With Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00331864

First received: April 11, 2006
Last updated: February 15, 2011
Last verified: February 2011
History of Changes

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Results First Received: December 9, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Age Related Macular Degeneration Choroidal Neovascularization
Intervention:	Drug: Ranibizumab

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
The study population consisted of two groups, one group being naïve to ranibizumab ("Non-ANCHOR" patients) and the other group were those patients who previously were treated with ranibizumab in the ANCHOR study (NCT00061594; "ANCHOR" patients).

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 Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Participant Flow: Overall Study

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
STARTED	**513**	**18**
COMPLETED	**455**	**14**

NOT COMPLETED	**58**	**4**
Adverse Event	**30**	**1**
Lack of Efficacy	**4**	**0**
Protocol Violation	**3**	**0**
Withdrawal by Subject	**10**	**0**
Lost to Follow-up	**4**	**3**
Administrative Problems	**1**	**0**
Death	**6**	**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 Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no

	sooner than 14 days after the previous treatment.
Total	Total of all reporting groups

Baseline Measures

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR	Total
Number of Participants [units: participants]	**513**	**18**	**531**
Age, Customized [units: participants]			
< 50 years	**1**	**0**	**1**
50 to < 65 years	**49**	**0**	**49**
65 to < 75 years	**173**	**5**	**178**
75 to < 85 years	**230**	**12**	**242**
≥ 85 years	**60**	**1**	**61**
Gender [units: participants]			
Female	**294**	**9**	**303**
Male	**219**	**9**	**228**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Patients With Ocular Adverse Events (AEs) in the Study Eye [Time Frame: Baseline through end of study (12 month treatment period)]

Measure Type	Primary

Measure Title	Percentage of Patients With Ocular Adverse Events (AEs) in the Study Eye
Measure Description	Percentage of patients with ocular adverse events in the study eye over the one year (12 month) treatment period.
Time Frame	Baseline through end of study (12 month treatment period)
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.
For Non-ANCHOR treatment group, the analysis population was the Safety population: All patients who had received at least one application of study drug and had at least one post-baseline safety assessment. For the ANCHOR treatment group, the analysis population was all enrolled patients.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	**Ranibizumab ANCHOR**
Number of Participants Analyzed [units: participants]	**513**	**18**
Percentage of Patients With Ocular Adverse Events (AEs) in the Study Eye		

[units: Percentage of Participants]	**48.5**	**38.9**

No statistical analysis provided for Percentage of Patients With Ocular Adverse Events (AEs) in the Study Eye

2. Primary: Percentage of Patients With Targeted Grade 3 Adverse Events (AEs) in the Study Eye [Time Frame: Baseline through end of study (12 month treatment period)]

Measure Type	Primary
Measure Title	Percentage of Patients With Targeted Grade 3 Adverse Events (AEs) in the Study Eye
Measure Description	Grade 3 targeted AEs included: • 4+ ocular inflammation or 2–3+ ocular inflammation failing to decrease to ≤ 1+ within 30 days • ≥ 30 letter decrease in BCVA that developed within 14 days of ranibizumab injection • sustained (>15 minutes) loss of light perception due to elevated intraocular pressure (IOP) or a >20 mm Hg change in IOP persisting longer than 14 days • new retinal tear or detachment involving the macula • new vitreous hemorrhage >2+ severity not resolving within 14 days • new or increase of previous retinal hemorrhage >1 disc area in size and involving the fovea
Time Frame	Baseline through end of study (12 month treatment period)
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.
For Non-ANCHOR treatment group, the analysis population was the Safety population: All patients who had received at least one application of study drug and had at least one post-baseline safety assessment. For the ANCHOR treatment group, the analysis population was all enrolled patients.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Number of Participants Analyzed [units: participants]	**513**	**18**
Percentage of Patients With Targeted Grade 3 Adverse Events (AEs) in the Study Eye [units: Percentage of Participants]	**2.9**	**0.0**

No statistical analysis provided for Percentage of Patients With Targeted Grade 3 Adverse Events (AEs) in the Study Eye

3. Secondary: Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3 [Time Frame: Baseline and Month 3]

Measure Type	Secondary
Measure Title	Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3
Measure Description	BCVA was assessed using best correction determined from protocol refraction. BCVA 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. BCVA is measured by the number of letters a patient could correctly read on an eye chart; hence an increased score indicates improvement in acuity.
Time Frame	Baseline and Month 3
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.
Non-ANCHOR patients: Analysis of Intent-to-Treat (ITT) population (all patients who received study drug at least once and had at least one post-baseline efficacy assessment) using last observation carried forward (LOCF). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	**Ranibizumab ANCHOR**
Number of Participants Analyzed		

[units: participants]	**509**	**15**
Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3 [units: Letters on the ETDRS-like testing charts] Mean (Standard Deviation)		
Baseline	**56.2 (12.11)**	**47.2 (22.10)**
Change to Month 3	**5.8 (11.12)**	**1.9 (9.26)**

No statistical analysis provided for Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3

4. Secondary: Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12 [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12
Measure Description	BCVA was assessed using best correction determined from protocol refraction. BCVA 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. BCVA is measured by the number of letters a patient could correctly read on an eye chart; hence an increased score indicates improvement in acuity.
Time Frame	Baseline and 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.
Non-ANCHOR patients: Analysis of Intent-to-Treat (ITT) population (all patients who received study drug at least once and had at least one

post-baseline efficacy assessment) using last observation carried forward (LOCF). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Number of Participants Analyzed [units: participants]	**509**	**17**
Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12 [units: Letters on the ETDRS-like testing charts] Mean (Standard Deviation)		
Baseline	**56.2 (12.11)**	**47.2 (22.10)**
Change to Month 12	**3.6 (13.89)**	**1.6 (8.66)**

No statistical analysis provided for Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12

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

Measure Type	Secondary
Measure Title	Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 3
Measure Description	Central retinal thickness was assessed using optical coherence tomography (OCT). OCT imaging was performed by trained personnel at each site using the Zeiss Stratus OCT™ 3 with version A6.1 (or more recent) software. Analysis of the OCT images was performed by the investigator. A negative number indicates improvement (reduced thickness).
Time Frame	Baseline and Month 3
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.
Non-ANCHOR patients: Analysis of Intent-to-Treat (ITT) population (all patients who received study drug at least once and had at least one post-baseline efficacy assessment) using last observation carried forward (LOCF). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Number of Participants Analyzed [units: participants]	**507**	**15**
Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 3 [units: Micrometers] Mean (Standard Deviation)		
Baseline	**339.6 (109.38)**	**214.1 (64.92)**
Change to Month 3	**-101.1 (115.69)**	**36.3 (72.96)**

No statistical analysis provided for Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 3

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

Measure Type	Secondary
Measure Title	Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 12
Measure Description	Central retinal thickness was assessed using optical coherence tomography (OCT). OCT imaging was performed by trained personnel at each site using the Zeiss Stratus OCT™ 3 with version A6.1 (or more recent) software. Analysis of the OCT images was performed by the investigator. A negative number indicates improvement (reduced thickness).
Time Frame	Baseline and 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.
Non-ANCHOR patients: Analysis of Intent-to-Treat (ITT) population (all patients who received study drug at least once and had at least one post-baseline efficacy assessment) using last observation carried forward (LOCF). ANCHOR patients: Analysis of All Enrolled population (all

enrolled patients) using LOCF.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Number of Participants Analyzed [units: participants]	**507**	**17**
Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 12 [units: Micrometers] Mean (Standard Deviation)		
Baseline	**339.6 (109.38)**	**214.1 (64.92)**
Change to Month 12	**-91.5 (115.47)**	**39.3 (84.61)**

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

7. Secondary: Time to the First Retreatment After Month 2 [Time Frame: Month 2 to Month 11]

Measure Type	Secondary
Measure Title	Time to the First Retreatment After Month 2
Measure Description	Time to first re-treatment is calculated as time difference in months starting from Month 2 until the month of first re-treatment. Criteria for re-treatment: • a >5 letter decrease in BCVA (determined using EDRS charts) based upon the highest visual acuity score from any prior scheduled study visit (Months 0, 1, 2 or 3) • a >100 µm increase in central retinal thickness (determined using OCT) from the thinnest measurement from any prior scheduled study visit (Months 0, 1, 2 or 3)
Time Frame	Month 2 to Month 11
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 patients: All patients who received study drug at least once and had at least one post-baseline efficacy assessment. The ANCHOR patients were not included in this analysis.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR

Number of Participants Analyzed [units: participants]	**500**
Time to the First Retreatment After Month 2 [units: Months] Median (Inter-Quartile Range)	**2 (1 to 6)**

No statistical analysis provided for Time to the First Retreatment After Month 2

8. Secondary: Total Number of Treatments [Time Frame: Baseline (Month 0) to Month 11]

Measure Type	Secondary
Measure Title	Total Number of Treatments
Measure Description	Total number of treatments administered during the entire treatment period (Month 0 to 11).
Time Frame	Baseline (Month 0) to Month 11
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.
For Non-ANCHOR treatment group, the analysis population was the Safety population: All patients who had received at least one application of study drug and had at least one post-baseline safety assessment. For the ANCHOR treatment group, the analysis population was all enrolled patients.

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as

	individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Measured Values

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Number of Participants Analyzed [units: participants]	**513**	**18**
Total Number of Treatments [units: Treatments] Mean (Standard Deviation)	**5.6 (2.37)**	**1.1 (2.29)**

No statistical analysis provided for Total Number of Treatments

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Ranibizumab Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as

	individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Serious Adverse Events

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Total, serious adverse events		
# participants affected / at risk	**80/513 (15.59%)**	**4/18 (22.22%)**
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**1/18 (5.56%)**
Cardiac disorders		
Acute coronary syndrome † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Acute myocardial infarction † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**1/18 (5.56%)**
Angina pectoris † [1]		
# participants affected / at risk	**3/513 (0.58%)**	**0/18 (0.00%)**
Arrhythmia † [1]		
# participants affected / at risk	**3/513 (0.58%)**	**0/18 (0.00%)**
Atrial fibrillation † [1]		
# participants affected / at risk	**2/513 (0.39%)**	**1/18 (5.56%)**
Cardiac failure † [1]		
# participants affected / at risk	**6/513 (1.17%)**	**0/18 (0.00%)**

Cardiogenic shock † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Coronary artery disease † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Intracardiac thrombus † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Myocardial infarction † 1		
# participants affected / at risk	**5/513 (0.97%)**	**0/18 (0.00%)**
Myocardial ischaemia † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Silent myocardial infarction † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Vestibular disorder † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Eye disorders		
Cataract (Fellow eye) † 1		
# participants affected / at risk	**3/513 (0.58%)**	**0/18 (0.00%)**
Cataract (Study eye) † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Choroidal neovascularisation (Fellow eye) † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Retinal haemorrhage (Study eye) † 1		

# participants affected / at risk	2/513 (0.39%)	0/18 (0.00%)
Retinal pigment epithelial tear (Study eye) † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Visual acuity reduced (Study eye) † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Vitreous haemorrhage (Study eye) † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Gastrointestinal disorders		
Abdominal pain † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Duodenal ulcer † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Gastric haemorrhage † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Gastric ulcer haemorrhage † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Gastritis erosive † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Haematemesis † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Hiatus hernia † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Intestinal obstruction † [1]		
# participants affected / at risk	2/513 (0.39%)	0/18 (0.00%)
Pancreatitis † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)

General disorders		
Asthenia † [1]		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Chest pain † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Death † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Infections and infestations		
Bronchitis † [1]		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Bronchopneumonia † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Clostridium difficile colitis † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Gangrene † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Infected skin ulcer † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Pneumonia † [1]		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Respiratory tract infection † [1]		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Sepsis † [1]		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Urinary tract infection † [1]		

# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Injury, poisoning and procedural complications		
Contusion † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Fall † [1]		
# participants affected / at risk	0/513 (0.00%)	1/18 (5.56%)
Femur fracture † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Hip fracture † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Humerus fracture † [1]		
# participants affected / at risk	0/513 (0.00%)	1/18 (5.56%)
Joint injury † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Limb injury † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Lumbar vertebral fracture † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Pelvic fracture † [1]		
# participants affected / at risk	0/513 (0.00%)	1/18 (5.56%)
Rib fracture † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Road traffic accident † [1]		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Skeletal injury † [1]		

# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Upper limb fracture † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Wrist fracture † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Investigations		
Blood urine present † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Cardioactive drug level increased † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Diabetes mellitus inadequate control † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Metabolic acidosis † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	4/513 (0.78%)	0/18 (0.00%)
Mobility decreased † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Musculoskeletal chest pain † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Osteoporosis † 1		

# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Pain in extremity † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Spinal column stenosis † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Spinal osteoarthritis † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
B-cell lymphoma † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Bladder cancer † 1		
# participants affected / at risk	2/513 (0.39%)	0/18 (0.00%)
Breast cancer † 1		
# participants affected / at risk	3/513 (0.58%)	0/18 (0.00%)
Colon adenoma † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Colon cancer † 1		
# participants affected / at risk	3/513 (0.58%)	0/18 (0.00%)
Extranodal marginal zone B-cell lymphoma (MALT type) † 1		
# participants affected / at risk	0/513 (0.00%)	1/18 (5.56%)
Gastrointestinal neoplasm † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Laryngeal neoplasm † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Lymphoma † 1		

# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Metastases to lung † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Metastatic neoplasm † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Myelodysplastic syndrome † 1		
# participants affected / at risk	2/513 (0.39%)	0/18 (0.00%)
Neuroma † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Prostate cancer † 1		
# participants affected / at risk	2/513 (0.39%)	0/18 (0.00%)
Prostate cancer metastatic † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Renal cell carcinoma † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Renal neoplasm † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Thyroid cancer † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)
Cerebrovascular accident † 1		
# participants affected / at risk	1/513 (0.19%)	1/18 (5.56%)
Diabetic coma † 1		
# participants affected / at risk	1/513 (0.19%)	0/18 (0.00%)

Dizziness † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Hypoaesthesia † 1		
# participants affected / at risk	**0/513 (0.00%)**	**1/18 (5.56%)**
Presyncope † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Sciatica † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Syncope † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Transient ischaemic attack † 1		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Renal failure acute † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Renal failure chronic † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	**0/513 (0.00%)**	**1/18 (5.56%)**
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**

Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Dyspnoea † 1		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Lung disorder † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Pulmonary embolism † 1		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Pulmonary oedema † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Respiratory failure † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Skin and subcutaneous tissue disorders		
Skin ulcer † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Vascular disorders		
Aortic aneurysm rupture † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Arteriosclerosis † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Circulatory collapse † 1		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Deep vein thrombosis † 1		

# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Hypertension † 1		
# participants affected / at risk	**2/513 (0.39%)**	**0/18 (0.00%)**
Hypotension † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Peripheral embolism † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**
Poor peripheral circulation † 1		
# participants affected / at risk	**1/513 (0.19%)**	**0/18 (0.00%)**

† 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 Non-ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). The dose of 0.3 mg ranibizumab was administered monthly for three consecutive months. From Month 3 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab were injected as individually needed based on retreatment criteria described in the protocol. Ranibizumab was administered no

	sooner than 14 days after the previous treatment.
Ranibizumab ANCHOR	Patients received up to 12 intravitreal injections (Month 0 through Month 11). From Month 0 through Month 11, either 0.3 mg ranibizumab or, after implementation of an amendment to the protocol, 0.5 mg ranibizumab was injected if the patient met retreatment criteria described in the protocol. Ranibizumab was administered no sooner than 14 days after the previous treatment.

Other Adverse Events

	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Total, other (not including serious) adverse events		
# participants affected / at risk	**199/513 (38.79%)**	**8/18 (44.44%)**
Eye disorders		
Choroidal neovascularisation (Fellow eye) † [1]		
# participants affected / at risk	**16/513 (3.12%)**	**2/18 (11.11%)**
Choroidal neovascularisation (Study eye) † [1]		
# participants affected / at risk	**8/513 (1.56%)**	**2/18 (11.11%)**
Conjunctival haemorrhage (Study eye) † [1]		
# participants affected / at risk	**28/513 (5.46%)**	**0/18 (0.00%)**
Retinal haemorrhage (Fellow eye) † [1]		
# participants affected / at risk	**12/513 (2.34%)**	**2/18 (11.11%)**
Retinal haemorrhage (Study eye) † [1]		
# participants affected / at risk	**35/513 (6.82%)**	**5/18 (27.78%)**
Retinal oedema (Study eye) † [1]		
# participants affected / at risk	**8/513 (1.56%)**	**2/18 (11.11%)**
Visual acuity reduced (Fellow eye) † [1]		
# participants affected / at risk	**23/513 (4.48%)**	**1/18 (5.56%)**
Visual acuity reduced (Study eye) † [1]		

# participants affected / at risk	**94/513 (18.32%)**	**1/18 (5.56%)**
Investigations		
Intraocular pressure increased (Study eye) † 1		
# participants affected / at risk	**36/513 (7.02%)**	**0/18 (0.00%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**13/513 (2.53%)**	**1/18 (5.56%)**

† 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:	NCT00331864 History of Changes
Other Study ID Numbers:	**CRFB002A2303**
Study First Received:	April 11, 2006
Results First Received:	December 9, 2010
Last Updated:	February 15, 2011
Health Authority:	Australia: National Health and Medical Research Council