



Notice

Because of a lapse in government funding, the information on this website may not be up to date, transactions submitted via the website may not be processed, and the agency may not be able to respond to inquiries until appropriations are enacted. The NIH Clinical Center (the research hospital of NIH) is open. For more details about its operating status, please visit cc.nih.gov. Updates regarding government operating status and resumption of normal operations can be found at opm.gov.



National Library of Medicine
National Center for Biotechnology Information

Completed

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

ClinicalTrials.gov ID NCT00331864

Sponsor Novartis

Information provided by Novartis

Last Update Posted 2011-02-18

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2006-05-29	None (earliest version on record)
☐	2	2006-06-06	- Study Status - Study Design - Outcome Measures - Eligibility
☐	3	2006-12-18	- Study Identification - Study Status
☐	4	2007-02-01	- Study Status - Study Description - Conditions - Study Design

	Version	Date submitted (YYYY-MM-DD)	Changes
			• Outcome Measures • Eligibility
☐	5	2007-02-05	• Study Status • Contacts/Locations
☐	6	2007-09-13	• Study Status • Study Design • Contacts/Locations
☐	7	2007-10-04	• Recruitment Status • Study Status • Contacts/Locations
☐	8	2008-04-18	• Study Status • Sponsor/Collaborators • Study Design • Arms and Interventions • Contacts/Locations
☐	9	2008-10-30	• Recruitment Status • Study Status • Outcome Measures • Eligibility
☐	10	2010-12-09	• Study Identification • Study Status • Arms and Interventions • Outcome Measures • Eligibility • Contacts/Locations • Participant Flow • Baseline Characteristics • Outcome Measures (Results) • Adverse Events • More Information
☐	11	2011-02-15	• Study Status • Conditions • Arms and Interventions • Outcome Measures • Eligibility • Participant Flow • Baseline Characteristics • Outcome Measures (Results)

Study Details

Study Identification

Unique Protocol ID

CRFB002A2303

Brief Title

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

Official Title

A Phase IIb, Open-label, Multi-center 12 Month Study to Evaluate the Safety, Tolerability and Efficacy of Ranibizumab (0.3 mg and/or 0.5 mg) in Patients With Subfoveal Choroidal Neovascularization Secondary to Age-related Macular Degeneration

Secondary IDs

Study Status

Record Verification

2010-12

Overall Status

Completed

Study Start

2006-04

Primary Completion

2008-04 [Actual]

Study Completion

2008-04

First Submitted

2006-04-11

First Submitted that Met QC Criteria

2006-05-29

First Posted

2006-05-31 [Estimated]

Results First Submitted
2010-12-09
Results First Submitted That Met QC Criteria
2010-12-09
Results First Posted
2011-01-04 [Estimated]
Last Update Submitted that Met QC Criteria
2010-12-09
Last Update Posted
2011-01-04 [Estimated]

Sponsor/Collaborators

Sponsor
Novartis
Responsible Party
Collaborators

Oversight

U.S. FDA-regulated Drug
U.S. FDA-regulated Device
Data Monitoring

Study Description

Brief Summary
Ranibizumab is a humanised recombinant monoclonal antibody fragment targeted against human vascular endothelial growth factor A. This study will assess the safety and efficacy of ranibizumab administered on an as-needed dosing regimen in patients with subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).
Detailed Description

Conditions

Condition
Age-Related Macular Degeneration Choroidal Neovascularization
Keywords
AMD, ranibizumab

Study Design

Study Type
Interventional
Primary Purpose
Treatment
Study Phase
Phase 3
Interventional Study Model
Single Group Assignment
Number of Arms
2
Masking
None (Open Label)
Allocation
Non-Randomized
Enrollment
531 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 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.	Drug: Ranibizumab Non-ANCHOR - Other Names: • rhuFab V2
Experimental: Ranibizumab ANCHOR	Drug: Ranibizumab ANCHOR Other Names:

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.

◦ rhuFab V2

Outcome Measures

Primary Outcome Measures

1. Incidence of Ocular Adverse Events (AEs) in the Study Eye
Incidence of 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)]
2. Incidence of Targeted Grade 3 Adverse Events (AEs) in the Study Eye

Grade 3 targeted AEs included:
 - 4+ ocular inflammation or 2-3+ ocular inflammation failing to decrease to $\leq 1+$ 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)]

Secondary Outcome Measures

1. Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3
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.
[Time Frame: Baseline to Month 3]
2. Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12
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.
[Time Frame: Baseline to Month 12]
3. Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 3
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 to Month 3]
4. Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 12
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 to Month 12]
5. Time to the First Retreatment After Month 2
Time to first re-treatment is calculated as time difference in months starting from Month 2 until the month of first re-treatment.
[Time Frame: Month 2 to Month 11]
6. Total Number of Treatments

Total number of treatments administered during the entire treatment period (Month 0 to 11).
[Time Frame: Baseline (Month 0) to Month 11]

Eligibility

Minimum Age

50 Years

Maximum Age

Sex

All

Gender-based Eligibility

Gender Eligibility Description

Accepts Healthy Volunteers

No

Criteria

Patients who participated in this study included those who had completed participation in the study CRFB002A2301 (ANCHOR), newly diagnosed patients, as well as previously diagnosed patients who had had recent disease progression.

Inclusion Criteria:

- Male or female patients > 50 years of age
- Diagnosis of active primary or recurrent CNV secondary to AMD, including those with predominantly classic, minimally classic or occult lesions with no classic component
- The total area of CNV (including both classic and occult components) encompassed within the lesion must be >= 50% of the total lesion area
- The total lesion area must be <= 12 disc areas
- Patients who have a BCVA (best corrected visual acuity) score between 73 and 24 letters, inclusive, in the study eye using ETDRS-like (Early Treatment of Diabetic Retinopathy Study) grading charts (approximately 20/40 to 20/320)

Exclusion Criteria:

- Patients who have a BCVA of < 34 letters in both eyes (legally blind is defined as bilateral vision below 20/200 or less than 34 letters)
- Laser photocoagulation, treatment with intravitreal steroids, verteporfin photo dynamic therapy or pegaptanib sodium in the study eye within 30 days preceding Day 1
- Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, anecortave acetate, protein kinase C inhibitors, etc.)

Other protocol-defined inclusion/exclusion criteria may apply.

Contacts/Locations

Central Contact Person

Study Officials
- Name Novartis Customer Information - Role Study Chair - Affiliation Novartis - Including Sites in Germany
Location
Basel, Switzerland Facility: Novartis - 64 sites in 11 countries

IPD Sharing

IPD information

References

Citations
Links
Available IPD/Information

Document Section

Study Results

Participant Flow

Recruitment Details
[Not Specified]
Pre-assignment Details
[Not Specified]

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Period Title: Overall Study		
Started	513	18
Completed	455	14
Not Completed	58	4
Reason Not Completed		
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

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR	
Arm/Group Description	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.	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 c
Overall Number of Baseline Participants	513	18	
Baseline Analysis Population Description	[Not Specified]		

[Ex](#)

Age, Customized

Measure Type: Number | Unit of measure: Participants

Number Analyzed	513 participants	18 participants	
< 50	1	0	
50 to < 65	49	0	
65 to < 75	173	5	
75 to < 85	230	12	
=> 85	60	1	

Sex: Female, Male

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	513 participants	18 participants	
Female	294 57.3%	9 50.0%	
Male	219 42.7%	9 50.0%	

Outcome Measures

[Expand all](#) / [Collapse all](#)

1. Incidence of Ocular Adverse Events (AEs) in the Study Eye

Type: Primary | Time Frame: Baseline through end of study (12 month treatment period)

Description	Incidence of 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)	
Analysis Population Description	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.	
Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	513	18
Measure Type: Number Unit of Measure: Participants	249	7

2. Incidence of Targeted Grade 3 Adverse Events (AEs) in the Study Eye	
Type: Primary Time Frame: Baseline through end of study (12 month treatment period)	
Description	Grade 3 targeted AEs included: • 4+ ocular inflammation or 2-3+ ocular inflammation failing to decrease to $\leq 1+$ 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)
Analysis Population Description	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.

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	513	18
Measure Type: Number Unit of Measure: Participants	15	0

3. Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 3 Type: Secondary Time Frame: Baseline to Month 3	
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.
Time Frame	Baseline to Month 3
Analysis Population Description	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) and observed data (OD). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF and OD.

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	509	15
Mean (Standard Deviation) Unit of Measure: Letters on the ETDRS-like testing charts	5.8 (11.12)	1.9 (9.26)

4. Mean Change in Best Corrected Visual Acuity (BCVA) of the Study Eye From Baseline to Month 12 Type: Secondary Time Frame: Baseline to Month 12	
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.
Time Frame	Baseline to Month 12
Analysis Population Description	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) and observed data (OD). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF and OD.

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	509	17
Mean (Standard Deviation) Unit of Measure: Letters on the ETDRS-like testing charts	3.6 (13.89)	1.6 (8.66)

5. Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 3	
Type: Secondary Time Frame: Baseline to Month 3	
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 to Month 3
Analysis Population Description	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) and observed data (OD). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF and OD.

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	507	15
Mean (Standard Deviation) Unit of Measure: Micrometers	-101.1 (115.69)	36.3 (72.96)

6. Mean Change in Central Retinal Thickness of the Study Eye From Baseline to Month 12	
Type: Secondary Time Frame: Baseline to Month 12	
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 to Month 12
Analysis Population Description	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) and observed data (OD). ANCHOR patients: Analysis of All Enrolled population (all enrolled patients) using LOCF and OD.

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	507	17
Mean (Standard Deviation) Unit of Measure: Micrometers	-91.5 (115.47)	39.3 (84.61)

7. Time to the First Retreatment After Month 2 Type: Secondary Time Frame: Month 2 to Month 11	
Description	Time to first re-treatment is calculated as time difference in months starting from Month 2 until the month of first re-treatment.
Time Frame	Month 2 to Month 11
Analysis Population Description	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.
Arm/Group Title	Ranibizumab Non-ANCHOR
Arm/Group Description	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.
Overall Number of Participants Analyzed	500
Median (Inter-Quartile Range) Unit of Measure: Months	2 (1 to 6)

8. Total Number of Treatments Type: Secondary Time Frame: Baseline (Month 0) to Month 11	
Description	Total number of treatments administered during the entire treatment period (Month 0 to 11).
Time Frame	Baseline (Month 0) to Month 11

Analysis Population Description	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.	
Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.
Overall Number of Participants Analyzed	513	18
Mean (Standard Deviation) Unit of Measure: Number of treatments	5.6 (2.37)	1.1 (2.29)

Adverse Events

Time Frame		
[Not Specified]		
Adverse Event Reporting Description		
[Not Specified]		
Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
Arm/Group Description	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.	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.

[Ex](#)

All-Cause Mortality

Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
	Affected / at Risk (%)	Affected / at Risk (%)
Total	--/--	--/--
Serious Adverse Events		
Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
	Affected / at Risk (%)	Affected / at Risk (%)
Total	80/513 (15.59%)	4/18 (22.22%)
Blood and lymphatic system disorders		
Anaemia ^{†1}	1/513 (0.19%)	1/18 (5.56%)
Cardiac disorders		
Acute coronary syndrome ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Acute myocardial infarction ^{†1}	1/513 (0.19%)	1/18 (5.56%)
Angina pectoris ^{†1}	3/513 (0.58%)	0/18 (0.00%)
Arrhythmia ^{†1}	3/513 (0.58%)	0/18 (0.00%)
Atrial fibrillation ^{†1}	2/513 (0.39%)	1/18 (5.56%)
Cardiac failure ^{†1}	6/513 (1.17%)	0/18 (0.00%)
Cardiogenic shock ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Coronary artery disease ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Intracardiac thrombus ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Myocardial infarction ^{†1}	5/513 (0.97%)	0/18 (0.00%)
Myocardial ischaemia ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Silent myocardial infarction ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Ear and labyrinth disorders		
Vertigo ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Vestibular disorder ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Eye disorders		

Cataract (Fellow eye) ^{†1}	3/513 (0.58%)	0/18 (0.00%)
Cataract (Study eye) ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Choroidal neovascularisation (Fellow eye) ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Retinal haemorrhage (Study eye) ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Retinal pigment epithelial tear (Study eye) ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Visual acuity reduced (Study eye) ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Vitreous haemorrhage (Study eye) ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Gastrointestinal disorders		
Abdominal pain ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Duodenal ulcer ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Gastric haemorrhage ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Gastric ulcer haemorrhage ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Gastritis erosive ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Haematemesis ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Hiatus hernia ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Intestinal obstruction ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Pancreatitis ^{†1}	1/513 (0.19%)	0/18 (0.00%)
General disorders		
Asthenia ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Chest pain ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Death ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Infections and infestations		
Bronchitis ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Bronchopneumonia ^{†1}	1/513 (0.19%)	0/18 (0.00%)

Clostridium difficile colitis ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Gangrene ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Infected skin ulcer ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Pneumonia ^{† 1}	2/513 (0.39%)	0/18 (0.00%)
Respiratory tract infection ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Sepsis ^{† 1}	2/513 (0.39%)	0/18 (0.00%)
Urinary tract infection ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Injury, poisoning and procedural complications		
Contusion ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Fall ^{† 1}	0/513 (0.00%)	1/18 (5.56%)
Femur fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Hip fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Humerus fracture ^{† 1}	0/513 (0.00%)	1/18 (5.56%)
Joint injury ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Limb injury ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Lumbar vertebral fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Pelvic fracture ^{† 1}	0/513 (0.00%)	1/18 (5.56%)
Rib fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Road traffic accident ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Skeletal injury ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Upper limb fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Wrist fracture ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Investigations		
Blood urine present ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Cardioactive drug level increased ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Metabolism and nutrition disorders		
Dehydration ^{† 1}	1/513 (0.19%)	0/18 (0.00%)

Diabetes mellitus inadequate control ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Metabolic acidosis ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Musculoskeletal and connective tissue disorders		
Back pain ^{† 1}	4/513 (0.78%)	0/18 (0.00%)
Mobility decreased ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Musculoskeletal chest pain ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Osteoporosis ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Pain in extremity ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Spinal column stenosis ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Spinal osteoarthritis ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
B-cell lymphoma ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Bladder cancer ^{† 1}	2/513 (0.39%)	0/18 (0.00%)
Breast cancer ^{† 1}	3/513 (0.58%)	0/18 (0.00%)
Colon adenoma ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Colon cancer ^{† 1}	3/513 (0.58%)	0/18 (0.00%)
Extranodal marginal zone B-cell lymphoma (MALT type) ^{† 1}	0/513 (0.00%)	1/18 (5.56%)
Gastrointestinal neoplasm ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Laryngeal neoplasm ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Lymphoma ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Metastases to lung ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Metastatic neoplasm ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Myelodysplastic syndrome ^{† 1}	2/513 (0.39%)	0/18 (0.00%)
Neuroma ^{† 1}	1/513 (0.19%)	0/18 (0.00%)
Prostate cancer ^{† 1}	2/513 (0.39%)	0/18 (0.00%)

Prostate cancer metastatic ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Renal cell carcinoma ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Renal neoplasm ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Thyroid cancer ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Nervous system disorders		
Cerebral infarction ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Cerebrovascular accident ^{†1}	1/513 (0.19%)	1/18 (5.56%)
Diabetic coma ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Dizziness ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Hypoaesthesia ^{†1}	0/513 (0.00%)	1/18 (5.56%)
Presyncope ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Sciatica ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Syncope ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Transient ischaemic attack ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Renal and urinary disorders		
Renal failure ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Renal failure acute ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Renal failure chronic ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia ^{†1}	0/513 (0.00%)	1/18 (5.56%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Chronic obstructive pulmonary disease ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Dyspnoea ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Lung disorder ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Pleural effusion ^{†1}	1/513 (0.19%)	0/18 (0.00%)

Pulmonary embolism ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Pulmonary oedema ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Respiratory failure ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Skin and subcutaneous tissue disorders		
Skin ulcer ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Vascular disorders		
Aortic aneurysm rupture ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Arteriosclerosis ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Circulatory collapse ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Deep vein thrombosis ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Hypertension ^{†1}	2/513 (0.39%)	0/18 (0.00%)
Hypotension ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Peripheral embolism ^{†1}	1/513 (0.19%)	0/18 (0.00%)
Poor peripheral circulation ^{†1}	1/513 (0.19%)	0/18 (0.00%)
† Indicates events were collected by systematic assessment		
1 Term from vocabulary, MedDRA		
Other (Not Including Serious) Adverse Events		
Frequency Threshold for Reporting Other Adverse Events	5%	
Arm/Group Title	Ranibizumab Non-ANCHOR	Ranibizumab ANCHOR
	Affected / at Risk (%)	Affected / at Risk (%)
Total	199/513 (38.79%)	8/18 (44.44%)
Eye disorders		
Choroidal neovascularisation (Fellow eye) ^{†1}	16/513 (3.12%)	2/18 (11.11%)
Choroidal neovascularisation (Study eye) ^{†1}	8/513 (1.56%)	2/18 (11.11%)

Conjunctival haemorrhage (Study eye) † 1	28/513 (5.46%)	0/18 (0.00%)
Retinal haemorrhage (Fellow eye) † 1	12/513 (2.34%)	2/18 (11.11%)
Retinal haemorrhage (Study eye) † 1	35/513 (6.82%)	5/18 (27.78%)
Retinal oedema (Study eye) † 1	8/513 (1.56%)	2/18 (11.11%)
Visual acuity reduced (Fellow eye) † 1	23/513 (4.48%)	1/18 (5.56%)
Visual acuity reduced (Study eye) † 1	94/513 (18.32%)	1/18 (5.56%)
Investigations		
Intraocular pressure increased (Study eye) † 1	36/513 (7.02%)	0/18 (0.00%)
Nervous system disorders		
Headache † 1	13/513 (2.53%)	1/18 (5.56%)
† Indicates events were collected by systematic assessment		
1 Term from vocabulary, MedDRA		

Limitations and Caveats

Description
[Not Specified]

More Information

Certain Agreements	
Principal investigators are NOT employed by the organization sponsoring the study.	
There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.	
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/Official Title	Study Director
Organization	Novartis Pharmaceuticals
Phone	862-778-8300

Email

[HHS Vulnerability Disclosure](#)