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Comparison of Age-related Macular Degeneration Treatments Trials: Lucentis-Avastin Trial

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00593450

Recruitment Status : Completed
First Posted : January 15, 2008
Results First Posted : August 30, 2012
Last Update Posted : August 21, 2017

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Sponsor:
University of Pennsylvania

Collaborator:
National Eye Institute (NEI)

Information provided by (Responsible Party):
University of Pennsylvania

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Study Description

Go to

Brief Summary:

The purpose of the study is to evaluate the relative efficacy and safety of treatment of neovascular AMD with Lucentis on a fixed schedule, Avastin on a fixed schedule, Lucentis on a variable schedule, and Avastin on a variable schedule.

A five year follow-up visit is being conducted in 2014 to gather information on long term outcomes.

Condition or disease	Intervention/treatment	Phase
Age Related Macular Degeneration	Drug: ranibizumab Drug: bevacizumab	Phase 3

Detailed Description:

Age related macular degeneration (AMD) is the leading cause of severe vision loss in people over the age of 65 in the United States and other Western countries. More than 1.6 million people in the US currently have one or both eyes affected by the advanced stage of AMD.

Lucentis® is the most effective treatment for neovascular AMD studied to date. Bevacizumab (Avastin®) and Lucentis® are derived from the same monoclonal antibody. Following the encouraging clinical trial results with Lucentis®, several investigators began evaluating intravitreal Avastin® for the treatment of CNV. Given its molecular similarity to Lucentis, its low cost, and its availability, the interest in Avastin® has been considerable. Avastin® has not been evaluated relative to Lucentis®.

In addition, previous studies do not answer the question of whether a reduced dosing schedule is as effective as a fixed schedule of monthly injections. Treatment dependent on clinical response has the potential to reduce the treatment burden to patients as well as to reduce the overall cost of therapy.

Only a single eye in each patient was analyzed.

At the five year follow-up visit, the subjects will undergo the same examinations and procedures as in the original study; however, the five year follow-up visit deos not involve any study treatment.

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	1208 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Comparison of Age-related Macular Degeneration Treatments Trials: Lucentis-Avastin Trial (CATT)
Actual Study Start Date :	February 2008
Actual Primary Completion Date :	December 2010
Actual Study Completion Date :	April 2015

Resource links provided by the National Library of Medicine NLM

MedlinePlus Genetics related topics: Age-related macular degeneration

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Bevacizumab Ranibizumab

U.S. FDA Resources

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Arm	Intervention/treatment
Active Comparator: 1 Lucentis® on a fixed schedule of every 4 weeks for 1 year; at 1 year, re-randomization to Lucentis® every 4 weeks or to variable dosing.	Drug: ranibizumab • 0.5 mg (0.05 mL)intravitreal injection Other Name: Lucentis
Experimental: 2 Avastin® on a fixed schedule of every 4 weeks for 1 year; at 1 year, re-randomization to Avastin® every 4 weeks or to variable dosing.	Drug: bevacizumab • 1.25 mg (0.05 mL)intravitreal injection Other Name: Avastin
Experimental: 3 Lucentis® on a variable dosing schedule for 2 years; i.e., after initial treatment, monthly evaluation for treatment based on signs of lesion activity.	Drug: ranibizumab • 0.5 mg (0.05 mL)intravitreal injection Other Name: Lucentis
Experimental: 4 Avastin® on a variable dosing schedule for 2 years; i.e., after initial treatment, monthly evaluation for treatment based on signs of lesion activity.	Drug: bevacizumab • 1.25 mg (0.05 mL)intravitreal injection Other Name: Avastin

Outcome Measures

Go to

Primary Outcome Measures :

1. Change From Baseline in Visual-acuity Score (Continuous) [Time Frame: Baseline and 1 Year]

   Visual acuity testing was performed with the Electronic Visual Tester (EVA) following the ETDRS protocol. VA score is measured as number of letters read correctly. The VA score change is the difference of the VA score at 1 Year and the VA score at baseline.

   In this study, the outcome VA score change is ranged from -71 to 52, with the higher VA score change the better visual acuity improvement.

Secondary Outcome Measures :

1. Change From Baseline Visual-acuity Score (Frequency) [Time Frame: Baseline and 1 Year]
2. Visual-acuity Score and Snellen Equivalent (Frequency) [Time Frame: at 1 Year]
3. Visual-acuity Score and Snellen Equivalent (Continuous) [Time Frame: at 1 Year]

   Visual acuity testing was performed with the Electronic Visual Tester (EVA) following the ETDRS protocol. VA score is measured as number of letters read correctly.

   In this study, the outcome VA score is ranged from 0 to 97, with the higher score the better visual acuity.

4. Number of Treatments [Time Frame: 1 Year]

   Cumulative over the 1 year of trial

5. Average Cost of Drug/Patient [Time Frame: at 1 Year]
6. Total Thickness at Fovea [Time Frame: at 1 Year]
7. Total Thickness Change From Baseline at Fovea [Time Frame: Baseline and 1 Year]
8. Retinal Thickness Plus Subfoveal-fluid Thickness at Fovea [Time Frame: at 1 Year]
9. Retinal Thickness Plus Subfoveal-fluid Thickness Change From Baseline at Fovea [Time Frame: Baseline and 1 Year]
10. Fluid on Optical Coherence Tomography [Time Frame: at 1 Year]
11. Dye Leakage on Angiogram [Time Frame: at 1 Year]
12. Area of Lesion [Time Frame: at 1 Year]
13. Area of Lesion Change From Baseline [Time Frame: Baseline and 1 Year]
14. Change in Systolic Blood Pressure From Baseline [Time Frame: Baseline and 1 Year]
15. Change in Diastolic Blood Pressure From Baseline [Time Frame: Baseline and 1 Year]

Eligibility Criteria

Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	50 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Active, subfoveal choroidal neovascularization (CNV)
- Fibrosis < 50% of total lesion area
- Visual acuity (VA) 20/25-20/320
- Age ≥ 50 yrs
- At least 1 drusen (>63µ) in either eye or late AMD in fellow eye

Exclusion Criteria:

- Previous treatment for CNV in study eye
- Other progressive retinal disease likely to compromise VA
- Contraindications to injections with Lucentis or Avastin

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00593450***

Locations

▸ Show 59 study locations

Sponsors and Collaborators

University of Pennsylvania

National Eye Institute (NEI)

Investigators

Study Chair:	Daniel F Martin, MD	The Cleveland Clinic
Study Chair:	Stuart L Fine, MD	Study Vice-Chair, University of Pennsylvania
Study Director:	Maureen G Maguire, PhD	Director of Coordinating Center, University of Pennsylvania
Study Director:	Glenn Jaffe,, MD	Director of OCT Reading Center, Duke University
Principal Investigator:	Juan E Grunwald, MD	Principal Investigator of Photography Reading Center, Universisty of Pennsylvania

More Information

Go to

Additional Information:

Click here for more information about this study: Comparison of AMD Treatments Trials (CATT)

NEI Clinical Studies Database

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Responsible Party:	University of Pennsylvania
ClinicalTrials.gov Identifier:	NCT00593450 History of Changes
Other Study ID Numbers:	NEI-137
	U10EY017823 (U.S. NIH Grant/Contract)
First Posted:	January 15, 2008 Key Record Dates
Results First Posted:	August 30, 2012
Last Update Posted:	August 21, 2017
Last Verified:	July 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Available at https://hyperprod.cceb.med.upenn.edu/catt/catt_index.php

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by University of Pennsylvania:

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bevacizumab
ranibizumab
choroidal neovascularization

Additional relevant MeSH terms:

Macular Degeneration
Retinal Degeneration
Retinal Diseases
Eye Diseases
Bevacizumab
Ranibizumab
Antineoplastic Agents, Immunological
Antineoplastic Agents
Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Physiological Effects of Drugs
Growth Inhibitors

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