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ClinicalTrials.gov



DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)] INvestigation of Clinical Impact (DA VINCI)



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: NCT00789477

Recruitment Status ⓘ : Completed

First Posted ⓘ : November 11, 2008

Results First Posted ⓘ : September 9, 2014

Last Update Posted ⓘ : September 9, 2014

[View this study on the modernized ClinicalTrials.gov](#)

Sponsor:

Regeneron Pharmaceuticals

Collaborator:

Bayer

Information provided by (Responsible Party):

Regeneron Pharmaceuticals

[Study Details](#)[Tabular View](#)[Study Results](#)[Disclaimer](#)[How to Read a Study Record](#)

Study Description

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Brief Summary:

This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) in subjects with diabetic macular edema (DME). Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.

<u>Condition or disease</u> ⓘ	<u>Intervention/treatment</u> ⓘ	<u>Phase</u> ⓘ
Diabetic Macular Edema	Procedure: Laser Photocoagulation Drug: Intravitreal Aflibercept Injection	Phase 2

Detailed Description:

Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Study Design

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Study Type ⓘ :

Interventional (Clinical Trial)

Actual Enrollment ⓘ :

221 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:

Treatment

Official Title:

A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)

Study Start Date ⓘ :

December 2008

Actual Primary Completion Date ⓘ :

December 2009

Actual Study Completion Date ⓘ :

September 2010

Resource links provided by the National Library of Medicine
[MedlinePlus](#) related topics: [Edema](#)
[Drug Information](#) available for: [Aflibercept](#) [Ziv-aflibercept](#)
[U.S. FDA Resources](#)
Arms and InterventionsGo to

<u>Arm ⓘ</u>	<u>Intervention/treatment ⓘ</u>
Experimental: Intravitreal Aflibercept Injection .5Q4 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) .5 mg every 4 weeks	Drug: Intravitreal Aflibercept Injection Other Name: IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Experimental: Intravitreal Aflibercept Injection 2Q4 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2 mg every 4 weeks	Drug: Intravitreal Aflibercept Injection Other Name: IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Experimental: Intravitreal Aflibercept Injection 2Q8 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by every 8 weeks	Drug: Intravitreal Aflibercept Injection Other Name: IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Experimental: Intravitreal Aflibercept Injection 2PRN Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by PRN (as-needed) dosing according to the re-treatment criteria	Drug: Intravitreal Aflibercept Injection Other Name: IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Active Comparator: Laser Photocoagulation Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting	Procedure: Laser Photocoagulation laser every 16 weeks as needed Other Name: macular laser therapy

Arm ⓘ	Intervention/treatment ⓘ
at week 16; laser re- treatment was permitted no more than once every 16 weeks.	

Outcome Measures

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[Primary Outcome Measures](#) ⓘ :

1. Change in BCVA From Baseline to Week 24 - Last Observation Carried Forward (LOCF)

[Time Frame: At week 24]

Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Measurements were taken at every study visit.

Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).

[Secondary Outcome Measures](#) ⓘ :

1. Change in BCVA From Baseline to Week 52 - LOCF [Time Frame: At week 52]

Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).

2. Participants With Gains in ETDRS Letter Score of at Least 15 Letters - LOCF [Time Frame: At week 24 and week 52]

Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).

3. Change From Baseline in Central Retinal Thickness (CRT) as Assessed by Optical Coherence Tomography (OCT) - LOCF [Time Frame: At week 24 and week 52]

Retinal thickness was evaluated using OCT at every visit except week 1. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).

4. Number of Focal Laser Treatments [Time Frame: Week 1 to week 48]

Eligibility Criteria

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Information from the National Library of Medicine

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:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria**Inclusion Criteria:**

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts and Locations

Go to ▼

Information from the National Library of Medicine

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): **NCT00789477***

Locations**United States, California**

Artesia, California, United States, 90701
Beverly Hills, California, United States, 90211
Mountain View, California, United States, 94040
Pasadena, California, United States, 91105
Sacramento, California, United States, 95819
Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518
New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426
Fort Lauderdale, Florida, United States, 33334
Fort Myers, Florida, United States, 33912
Ocala, Florida, United States, 34474
Palm Beach Gardens, Florida, United States, 33410
Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Sponsors and Collaborators

Regeneron Pharmaceuticals

Bayer

Investigators

Study Director: Clinical Trial Management Regeneron Pharmaceuticals

More Information

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Responsible Party:

Regeneron Pharmaceuticals

ClinicalTrials.gov Identifier:

[NCT00789477](#) [History of Changes](#)

Other Study ID Numbers:

VGFT-OD-0706

First Posted:

November 11, 2008 [Key Record Dates](#)

Results First Posted:

September 9, 2014

Last Update Posted:

September 9, 2014

Last Verified:

August 2014

Additional relevant MeSH terms:

Macular Edema
Macular Degeneration
Retinal Degeneration
Retinal Diseases
Eye Diseases
Aflibercept
Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Physiological Effects of Drugs
Growth Inhibitors
Antineoplastic Agents