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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 or investigator. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for detail.

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 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.

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
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](#)[S FDA Resource](#)**Arms and Interventions**

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Arm ⓘ	Intervention/treatment ⓘ
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 week for 3 visits followed by every 8 week	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 week for 3 visits followed by PRN (as needed) dosing according to the retreatment 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 meter Measurement were taken at every study visit

Missing values were imputed with post baseline value 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 meter Missing values were imputed with post baseline value 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 Treatment [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:

8 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
- Adult 18 year or older with type 1 or 2 diabete mellitu 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***

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Spon or and Collaborator

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nvestigators

Study Director: Clinical Trial Management Regeneron Pharmaceuticals

More Information

Go to 

Responsible Party:

Regeneron Pharmaceuticals

ClinicalTrials.gov Identifier:[CT00789477](#) [History of Changes](#)**Other Study ID Numbers:**

GFT-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