ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 07/10/2014

ClinicalTrials.gov ID: NCT00168389

Study Identification

Unique Protocol ID:	206207-010
Brief Title:	A Study of the Safety and Efficacy of a New Treatment for Diabetic Macular Edema
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	July 2014
Overall Status:	Completed
Study Start:	February 2005
Primary Completion:	June 2012 [Actual]
Study Completion:	June 2012 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 58,663 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the safety and efficacy of an intravitreal implant of dexamethasone for the treatment of diabetic macular edema.
Detailed Description:	

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 494 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Dexamethasone 700 µg 700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.	Drug: Dexamethasone 350 µg or 700 µg dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months. Other Names: • Posurdex® • Ozurdex®
Experimental: Dexamethasone 350 µg 350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.	Drug: Dexamethasone 350 µg or 700 µg dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months. Other Names: • Posurdex® • Ozurdex®
Sham Comparator: Sham Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.	Sham Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Key Inclusion Criteria:

- 18 years of age or older with diabetic macular edema;
- Decrease in visual acuity in at least one eye as a result of macular edema (20/50 or worse);
- Visual acuity in other eye no worse than 20/200

Key Exclusion Criteria:

- Known anticipated need for ocular surgery within first 12 months of study;
- History of glaucoma or current high eye pressure requiring more than 1 medication;
- Uncontrolled systemic disease;
- Known steroid-responder;
- Use of systemic steroids
- Use of Warfarin/Heparin

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc

Locations: United States, California
Inglewood, California, United States

Canada, Ontario
Toronto, Ontario, Canada

Austria
Graz, Austria

Czech Republic
Prague, Czech Republic

Germany
Hamburg, Germany

Spain
Barcelona, Spain

Israel
Tel Aviv, Israel

Philippines
Rockwell Center, Makati, Philippines

Portugal
Coimbra, Portugal

South Africa
Cape Town, South Africa

Australia, New South Wales
Westmead, New South Wales, Australia

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Overall Study

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Started	163	166	165
Completed	107	118	70
Not Completed	56	48	95

Baseline Characteristics

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Baseline Measures

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham	Total
Number of Participants	163	166	165	494
Age, Customized [units: Participants]				
<45 years	4	5	7	16
45 to 65 years	89	97	95	281
>65 years	70	64	63	197
Gender, Male/Female [units: Participants]				
Female	61	66	63	190
Male	102	100	102	304

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients With a Best Corrected Visual Acuity (BCVA) Improvement of ≥15 Letters From Baseline in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). An increase in the number of letters read correctly indicates improvement and a decrease in the number of letters read correctly indicates a worsening.
Time Frame	Baseline, Month 39/Final Visit

Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
Percentage of Patients With a Best Corrected Visual Acuity (BCVA) Improvement of ≥15 Letters From Baseline in the Study Eye [units: Percentage of Patients]	22.1	18.7	13.3

2. Secondary Outcome Measure:

Measure Title	Average Change From Baseline in BCVA in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). The average BCVA is calculated across study visits for each patient. A positive number change from baseline indicates an improvement and a negative number change from baseline indicates a worsening.
Time Frame	Baseline, 39 Months
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
Average Change From Baseline in BCVA in the Study Eye [units: Letters] Mean (Standard Deviation)			
Baseline	56.2 (10.5)	55.9 (9.64)	56.8 (8.66)
Average Change from Baseline Over 39 Months	4.1 (8.26)	4.3 (8.49)	1.9 (7.74)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in BCVA in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). A positive number change from baseline indicates an improvement and a negative number change from baseline indicates a worsening.
Time Frame	Baseline, Month 39/Final Visit
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
Change From Baseline in BCVA in the Study Eye [units: Letters] Mean (Standard Deviation)			
Baseline	56.2 (10.5)	55.9 (9.64)	56.8 (8.66)
Change from Baseline at Month 39/Final Visit	4.1 (13.89)	5.0 (11.97)	0.8 (11.89)

4. Secondary Outcome Measure:

Measure Title	Percentage of Patients With a BCVA Improvement of ≥10 Letters From Baseline in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). An increase in the number of letters read correctly indicates improvement and a decrease in the number of letters read correctly indicates a worsening.
Time Frame	Baseline, Month 39/Final Visit
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.

	Description
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
Percentage of Patients With a BCVA Improvement of ≥10 Letters From Baseline in the Study Eye [units: Percentage of Patients]	38.7	34.3	23.0

5. Secondary Outcome Measure:

Measure Title	Average Change From Baseline in Retinal Thickness as Measured by Optical Coherence Tomography (OCT)
Measure Description	OCT is a laser-based, noninvasive, diagnostic system that provides high-resolution, three-dimensional images of the retina from which retinal thickness can be measured. The average OCT retinal thickness is calculated across study visits for each patient. A negative number change from baseline indicates an improvement and a positive number change from baseline indicates a worsening.
Time Frame	Baseline, 39 Months
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients with data at the time point

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	162	165	165
Average Change From Baseline in Retinal Thickness as Measured by Optical Coherence Tomography (OCT) [units: Microns] Mean (Standard Deviation)			
Baseline	436.7 (145.88)	457.4 (158.09)	468.7 (129.61)
Average Change from Baseline Over 39 Months	-101.1 (119.17)	-103.9 (137.88)	-37.8 (103.96)

6. Secondary Outcome Measure:

Measure Title	10th Percentile for Time to BCVA Improvement of ≥15 Letters From Baseline in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). Shorter durations of time to improvement are best. The 10th percentile represents the first 10% of patients to reach a BCVA improvement of ≥15 letters from baseline in the study eye.
Time Frame	Baseline, 39 Months
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
10th Percentile for Time to BCVA Improvement of ≥15 Letters From Baseline in the Study Eye [units: Days]	50	51	150

7. Secondary Outcome Measure:

Measure Title	Percentage of Patients With BCVA Improvement of ≥15 Letters From Baseline in the Study Eye at 3-month Intervals
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). An increase in the number of letters read correctly indicates improvement and a decrease in the number of letters read correctly indicates a worsening.
Time Frame	Baseline, Month 3, Month 6, Month 9, Month 12, Month 15, Month 18, Month 21, Month 24, Month 27, Month 30, Month 33, Month 36, Month 39/Final Visit
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	163	166	165
Percentage of Patients With BCVA Improvement of ≥15 Letters From Baseline in the Study Eye at 3-month Intervals			

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
[units: Percentage of Patients]			
Month 3	14.1	13.9	6.1
Month 6	14.1	10.2	7.9
Month 9	19.0	18.1	8.5
Month 12	13.5	15.1	9.1
Month 15	15.3	16.3	7.3
Month 18	17.2	9.6	10.9
Month 21	16.6	15.1	9.1
Month 24	14.1	15.1	10.9
Month 27	20.2	19.3	12.7
Month 30	16.6	19.9	11.5
Month 33	22.1	17.5	11.5
Month 36	20.9	19.9	12.7
Month 39/Final Visit	22.1	18.7	13.3

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The Safety Population included all treated patients and was used for adverse event (AE) and Serious Adverse Event (SAE) reporting.

Reporting Groups

	Description
Dexamethasone 700 µg	700 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.
Dexamethasone 350 µg	350 µg Dexamethasone posterior segment drug delivery system - injection into the vitreous cavity not less than every 6 months for up to 36 months.

	Description
Sham	Sham posterior segment drug delivery system - needle-less drug delivery system without study medication not less than every 6 months for up to 36 months.

Serious Adverse Events

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	52/160 (32.5%)	52/165 (31.52%)	34/164 (20.73%)
Cardiac disorders			
Acute Coronary Syndrome [A] †	0/160 (0%)	2/165 (1.21%)	0/164 (0%)
Acute Myocardial Infarction [A] †	1/160 (0.63%)	1/165 (0.61%)	2/164 (1.22%)
Angina Pectoris [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Angina Unstable [A] †	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Aortic Valve Stenosis [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Arrhythmia [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Atrial Fibrillation [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Atrioventricular Block Complete [A] †	2/160 (1.25%)	1/165 (0.61%)	2/164 (1.22%)
Cardiac Arrest [A] †	1/160 (0.63%)	0/165 (0%)	1/164 (0.61%)
Cardiac Failure Congestive [A] †	2/160 (1.25%)	3/165 (1.82%)	1/164 (0.61%)
Cardiac disorder [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Coronary Artery Disease [A] †	0/160 (0%)	1/165 (0.61%)	2/164 (1.22%)
Coronary Artery Occlusion [A] †	2/160 (1.25%)	0/165 (0%)	0/164 (0%)
Ischaemic Cardiomyopathy [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Myocardial Infarction [A] †	0/160 (0%)	5/165 (3.03%)	2/164 (1.22%)
Myocardial Ischaemia [A] †	0/160 (0%)	2/165 (1.21%)	2/164 (1.22%)
Pleuropericarditis [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Sick Sinus Syndrome [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Tachycardia [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Ear and labyrinth disorders			
Vertigo [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Endocrine disorders			
Goitre [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Eye disorders			
Angle Closure Glaucoma [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Anterior Chamber Fibrin [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Cataract [A] †	2/160 (1.25%)	2/165 (1.21%)	1/164 (0.61%)
Cataract Subcapsular [A] †	1/160 (0.63%)	2/165 (1.21%)	0/164 (0%)
Corneal Erosion [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Diabetic Retinal Oedema [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Iridocyclitis [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Lens Dislocation [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Macular oedema [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Open Angle Glaucoma [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Pupillary Block [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Retinal Detachment [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Vitreous Adhesions [A] †	1/160 (0.63%)	1/165 (0.61%)	1/164 (0.61%)
Vitreous Haemorrhage [A] †	2/160 (1.25%)	3/165 (1.82%)	1/164 (0.61%)
Gastrointestinal disorders			
Duodenal Fistula [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal Haemorrhage [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Gastrointestinal Ulcer Haemorrhage [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Intestinal Perforation [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
General disorders			
Drug Intolerance [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Multi-Organ Failure [A] †	2/160 (1.25%)	0/165 (0%)	0/164 (0%)
Non-Cardiac Chest Pain [A] *	2/160 (1.25%)	0/165 (0%)	2/164 (1.22%)
Hepatobiliary disorders			
Bile Duct Stone [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Hepatic Failure [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Liver Disorder [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Infections and infestations			
Abscess of Salivary Gland [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Anal Abscess [A] *	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Bronchitis [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Bronchopneumonia [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Cellulitis [A] †	2/160 (1.25%)	2/165 (1.21%)	0/164 (0%)
Device Related Infection [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Diabetic Foot Infection [A] *	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Diabetic Gangrene [A] †	0/160 (0%)	2/165 (1.21%)	0/164 (0%)
Erysipelas [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Gangrene [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastroenteritis [A] *	2/160 (1.25%)	0/165 (0%)	0/164 (0%)
H1N1 Influenza [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Infectious Peritonitis [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Localised Infection [A] *	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Lung Abscess [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Osteomyelitis [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Pharyngeal Abscess [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Pneumonia [A] †	2/160 (1.25%)	2/165 (1.21%)	0/164 (0%)
Pneumonia Pneumococcal [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Pneumonia Streptococcal [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Postoperative Wound Infection [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Sepsis [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Urinary Tract Infection [A] †	0/160 (0%)	2/165 (1.21%)	0/164 (0%)
Wound Infection [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Injury, poisoning and procedural complications			
Chemical Eye Injury [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Chest Injury [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Fall [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Femoral Neck Fracture [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Femur Fracture [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Foot Fracture [A] †	0/160 (0%)	2/165 (1.21%)	0/164 (0%)
Humerus fracture [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ilium Fracture [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Incisional Hernia [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Laceration [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Limb Injury [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Lower Limb Fracture [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Open Wound [A] *	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Pelvic Fracture [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Post Procedural Haemorrhage [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Pubis Fracture [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Radius Fracture [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Rib Fracture [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Spinal Compression Fracture [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Spinal Fracture [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Subdural Haematoma [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Tendon Rupture [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Ulna Fracture [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Upper Limb Fracture [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Investigations			
Blood Glucose Fluctuation [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Intraocular Pressure Increased [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Metabolism and nutrition disorders			
Dehydration [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Diabetes Mellitus [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Hyperkalaemia [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Hypoglycaemia [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Arthritis [A] *	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Dupuytren's Contracture [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Intervertebral Disc Disorder [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Musculoskeletal Chest Pain [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Osteitis [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Osteoarthritis [A] *	1/160 (0.63%)	1/165 (0.61%)	1/164 (0.61%)
Pain in Extremity [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Rotator Cuff Syndrome [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Spinal Osteoarthritis [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Spondylolisthesis [A] †	0/160 (0%)	1/165 (0.61%)	1/164 (0.61%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma Pancreas [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Basal Cell Carcinoma [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Breast Cancer Metastatic [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Colon Cancer [A] †	1/160 (0.63%)	1/165 (0.61%)	1/164 (0.61%)
Colon Cancer Recurrent [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Lip Neoplasm Malignant Stage Unspecified [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Malignant Melanoma [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Non-Hodgkin's Lymphoma [A] †	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Pancreatic Carcinoma Metastatic [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Prostate Cancer [A] †	0/102 (0%)	2/100 (2%)	2/102 (1.96%)
Rectosigmoid Cancer [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Renal Cancer [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Small Cell Lung Cancer Metastatic [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Nervous system disorders			
Carotid Artery Occlusion [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Carotid Artery Stenosis [A] †	0/160 (0%)	2/165 (1.21%)	0/164 (0%)
Carpal Tunnel Syndrome [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Cerebrovascular Accident [A] †	3/160 (1.88%)	1/165 (0.61%)	1/164 (0.61%)
Epilepsy [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Ischaemic Stroke [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Muscle Spasticity [A] *	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Presyncope [A] *	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Syncope [A] *	1/160 (0.63%)	1/165 (0.61%)	1/164 (0.61%)
Transient Ischaemic Attack [A] †	2/160 (1.25%)	2/165 (1.21%)	0/164 (0%)
Tremor [A] *	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Renal and urinary disorders			
Azotaemia [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Bladder Prolapse [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Renal Failure [A] †	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Renal Failure Acute [A] †	2/160 (1.25%)	2/165 (1.21%)	0/164 (0%)
Renal Failure Chronic [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Distress Syndrome [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Acute Respiratory Failure [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Chronic Obstructive Pulmonary Disease [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Dyspnoea [A] *	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)
Pleural Effusion [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Skin and subcutaneous tissue disorders			
Diabetic Foot [A] †	0/160 (0%)	2/165 (1.21%)	1/164 (0.61%)
Pemphigoid [A] †	1/160 (0.63%)	0/165 (0%)	0/164 (0%)
Skin Ulcer [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Vascular disorders			
Aortic Aneurysm [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Deep Vein Thrombosis [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Hypertension [A] †	2/160 (1.25%)	0/165 (0%)	0/164 (0%)
Hypotension [A] †	0/160 (0%)	0/165 (0%)	1/164 (0.61%)
Intermittent Claudication [A] †	0/160 (0%)	1/165 (0.61%)	0/164 (0%)
Peripheral Arterial Occlusive Disease [A] †	1/160 (0.63%)	1/165 (0.61%)	0/164 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 15.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	153/160 (95.63%)	162/165 (98.18%)	124/164 (75.61%)
Eye disorders			
Cataract [A] †	63/160 (39.38%)	60/165 (36.36%)	15/164 (9.15%)
Cataract Nuclear [A] †	12/160 (7.5%)	10/165 (6.06%)	4/164 (2.44%)
Cataract Subcapsular [A] †	20/160 (12.5%)	21/165 (12.73%)	8/164 (4.88%)
Conjunctival Haemorrhage [A] †	37/160 (23.13%)	53/165 (32.12%)	17/164 (10.37%)
Conjunctival Hyperaemia [A] †	12/160 (7.5%)	18/165 (10.91%)	9/164 (5.49%)
Conjunctivitis [A] †	15/160 (9.38%)	8/165 (4.85%)	7/164 (4.27%)
Diabetic Retinopathy [A] †	10/160 (6.25%)	5/165 (3.03%)	4/164 (2.44%)
Dry Eye [A] *	8/160 (5%)	10/165 (6.06%)	4/164 (2.44%)
Eye Pain [A] *	11/160 (6.88%)	12/165 (7.27%)	6/164 (3.66%)
Macular Oedema [A] †	21/160 (13.12%)	15/165 (9.09%)	16/164 (9.76%)
Macular fibrosis [A] †	9/160 (5.62%)	14/165 (8.48%)	6/164 (3.66%)
Posterior Capsule Opacification [A] †	9/160 (5.62%)	12/165 (7.27%)	3/164 (1.83%)
Retinal Exudates [A] †	4/160 (2.5%)	7/165 (4.24%)	9/164 (5.49%)
Retinal Haemorrhage [A] †	11/160 (6.88%)	11/165 (6.67%)	7/164 (4.27%)
Visual Acuity Reduced [A] *	6/160 (3.75%)	11/165 (6.67%)	6/164 (3.66%)
Vitreous Detachment [A] †	7/160 (4.37%)	10/165 (6.06%)	4/164 (2.44%)
Vitreous Floaters [A] †	8/160 (5%)	4/165 (2.42%)	2/164 (1.22%)
Vitreous Haemorrhage [A] †	18/160 (11.25%)	35/165 (21.21%)	10/164 (6.1%)
Infections and infestations			

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nasopharyngitis [A] *	13/160 (8.12%)	8/165 (4.85%)	16/164 (9.76%)
Upper Respiratory Tract Infection [A] *	6/160 (3.75%)	6/165 (3.64%)	10/164 (6.1%)
Investigations			
Intraocular Pressure Increased [A] †	66/160 (41.25%)	62/165 (37.58%)	8/164 (4.88%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] *	3/160 (1.88%)	10/165 (6.06%)	2/164 (1.22%)
Vascular disorders			
Hypertension [A] †	17/160 (10.63%)	19/165 (11.52%)	12/164 (7.32%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 15.0

Limitations and Caveats

[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.

A 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 90 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head,
Organization: Allergan, Inc
Phone: 714-246-4500

Email: clinicaltrials@allergan.com