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

ClinicalTrials.gov ID: NCT00168337

Study Identification

Unique Protocol ID:	206207-011
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:	May 2005
Primary Completion:	May 2012 [Actual]
Study Completion:	May 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: 554 [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 next 12 months;
- 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
Artesia, California, United States

Brazil
Sao Paulo, Brazil

Colombia
Bogota, Colombia

France
Dijon, France

United Kingdom
London, United Kingdom

Hungary
Budapest, Hungary

Italy
Florence, Italy

India
New Delhi, India

Korea, Republic of
Seoul, Korea, Republic of

New Zealand
Auckland, New Zealand

Italy
Milano, Italy

Taiwan
Taipei, Taiwan

Canada, Ontario
Mississauga, Ontario, Canada

Singapore
Singapore, Singapore

Poland
Warszawa, Poland

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	188	181	185
Completed	118	112	82
Not Completed	70	69	103

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	188	181	185	554
Age, Customized [units: Participants]				
<45 years	2	8	6	16
45 to 65 years	116	109	108	333
>65 years	70	64	71	205
Gender, Male/Female [units: Participants]				
Female	77	75	70	222
Male	111	106	115	332

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	188	181	185
Percentage of Patients With a Best Corrected Visual Acuity (BCVA) Improvement of ≥15 Letters From Baseline in the Study Eye [units: Percentage of Patients]	22.3	18.2	10.8

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	188	181	185
Average Change From Baseline in BCVA in the Study Eye [units: Letters] Mean (Standard Deviation)			
Baseline	55.9 (9.83)	55.2 (9.69)	57.0 (8.76)
Average Change from Baseline Over 39 months	2.9 (8.55)	2.9 (7.67)	2.0 (8.20)

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	188	181	185
Change From Baseline in BCVA in the Study Eye [units: Letters] Mean (Standard Deviation)			
Baseline	55.9 (9.83)	55.2 (9.69)	57.0 (8.76)
Change from Baseline at Month 39/Final Visit	1.3 (17.03)	1.4 (15.17)	-0.0 (15.41)

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.
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	188	181	185
Percentage of Patients With a BCVA Improvement of ≥10 Letters From Baseline in the Study Eye [units: Percentage of Patients]	34.6	29.8	24.9

5. Secondary Outcome Measure:

Measure Title	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. A negative number change from baseline indicates an improvement and a positive 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.

	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	186	179	177
Change From Baseline in Retinal Thickness as Measured by Optical Coherence Tomography (OCT) [units: Microns] Mean (Standard Deviation)			
Baseline	486.0 (163.12)	475.4 (160.70)	453.7 (135.36)
Change from Baseline at Month 39/Final Visit	-117.9 (227.16)	-131.2 (204.33)	-70.4 (180.82)

6. Post-Hoc 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.

	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.

Measured Values

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
Number of Participants Analyzed	188	181	185
10th Percentile for Time to BCVA Improvement of ≥15 Letters From Baseline in the Study Eye [units: Days]	50	49	186

7. Post-Hoc 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	188	181	185
Percentage of Patients With BCVA Improvement of ≥15 Letters From Baseline in the Study Eye at 3-month Intervals [units: Percentage of Patients]			
Month 3	11.7	14.4	2.7
Month 6	8.5	6.1	3.2
Month 9	15.4	14.4	7.0
Month 12	12.8	9.9	9.7
Month 15	12.8	14.4	9.7
Month 18	12.2	10.5	9.2
Month 21	15.4	9.4	10.3
Month 24	18.1	9.4	10.3
Month 27	16.5	12.2	10.3
Month 30	18.6	12.2	10.3
Month 33	18.6	14.4	9.7
Month 36	19.7	16.6	10.8
Month 39/Final Visit	22.3	18.2	10.8

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.
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	63/187 (33.69%)	68/178 (38.2%)	49/186 (26.34%)
Blood and lymphatic system disorders			
Anaemia [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Anaemia of Chronic Disease [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Pancytopenia [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Cardiac disorders			
Acute Coronary Syndrome [A] †	2/187 (1.07%)	0/178 (0%)	0/186 (0%)
Acute Myocardial Infarction [A] †	1/187 (0.53%)	0/178 (0%)	1/186 (0.54%)
Angina Pectoris [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Angina Unstable [A] †	1/187 (0.53%)	1/178 (0.56%)	0/186 (0%)
Arrhythmia [A] †	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Atrial Flutter [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Atrioventricular Block [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Atrioventricular Block Second Degree [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Bradycardia [A] †	1/187 (0.53%)	1/178 (0.56%)	0/186 (0%)
Cardiac Arrest [A] †	0/187 (0%)	3/178 (1.69%)	1/186 (0.54%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac Disorder [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cardiac Failure [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cardiac Failure Congestive [A] †	1/187 (0.53%)	6/178 (3.37%)	1/186 (0.54%)
Cardiomyopathy [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Coronary Artery Disease [A] †	3/187 (1.6%)	3/178 (1.69%)	1/186 (0.54%)
Coronary Artery Insufficiency [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Ischaemic Cardiomyopathy [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Mitral Valve Incompetence [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Myocardial Infarction [A] †	1/187 (0.53%)	4/178 (2.25%)	2/186 (1.08%)
Myocardial Ischaemia [A] †	1/187 (0.53%)	0/178 (0%)	1/186 (0.54%)
Pulseless Electrical Activity [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Ventricular Fibrillation [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Ear and labyrinth disorders			
Vertigo Positional [A] *	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Eye disorders			
Cataract [A] †	8/187 (4.28%)	7/178 (3.93%)	2/186 (1.08%)
Cataract Cortical [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cataract Subcapsular [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Cystoid Macular Oedema [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Diabetic Retinal Oedema [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Diabetic Retinopathy [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Glaucoma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hyalosis Asteroid [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Macular Fibrosis [A] †	2/187 (1.07%)	1/178 (0.56%)	2/186 (1.08%)
Macular Oedema [A] †	2/187 (1.07%)	3/178 (1.69%)	0/186 (0%)
Necrotising Retinitis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Open Angle Glaucoma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Retinal Detachment [A] †	2/187 (1.07%)	0/178 (0%)	0/186 (0%)
Vitreous Haemorrhage [A] †	8/187 (4.28%)	2/178 (1.12%)	4/186 (2.15%)
Gastrointestinal disorders			
Abdominal Hernia [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Colonic Polyp [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Diarrhoea [A] *	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Faecaloma [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Gastric Ulcer [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Gastritis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Gastrointestinal Haemorrhage [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Gastrointestinal Hypomotility [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Inguinal Hernia [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Oesophagitis [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Pancreatitis Acute [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Small Intestinal Perforation [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
General disorders			
Chest Pain [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Device Dislocation [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Medical Device Complication [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Multi-Organ Failure [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Pelvic Mass [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Sudden Death [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Hepatobiliary disorders			
Cholecystitis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cholecystitis Acute [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Cholelithiasis [A] †	1/187 (0.53%)	0/178 (0%)	2/186 (1.08%)
Hepatic Cirrhosis [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Infections and infestations			
Appendicitis [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Arthritis Bacterial [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Bronchopneumonia [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Cellulitis [A] †	3/187 (1.6%)	3/178 (1.69%)	1/186 (0.54%)
Endophthalmitis [A] †	2/187 (1.07%)	1/178 (0.56%)	0/186 (0%)
Gallbladder Empyema [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Gangrene [A] †	0/187 (0%)	0/178 (0%)	2/186 (1.08%)
Gastroenteritis [A] *	1/187 (0.53%)	1/178 (0.56%)	0/186 (0%)
Incision Site Infection [A] *	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Labyrinthitis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Localised Infection [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Osteomyelitis [A] †	1/187 (0.53%)	2/178 (1.12%)	1/186 (0.54%)
Otitis media [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Pneumonia [A] †	2/187 (1.07%)	2/178 (1.12%)	0/186 (0%)
Pneumonia Viral [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Pyelonephritis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Septic Shock [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Staphylococcal Sepsis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Tuberculosis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Urinary Tract Infection [A] †	2/187 (1.07%)	2/178 (1.12%)	0/186 (0%)
Urosepsis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Injury, poisoning and procedural complications			
Cartilage Injury [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Comminuted Fracture [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Craniocerebral Injury [A] *	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Femoral Neck Fracture [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Femur Fracture [A] †	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Fibula Fracture [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Humerus Fracture [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
In-Stent Coronary Artery Restenosis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Ligament Sprain [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Limb Injury [A] *	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Lower Limb Fracture [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Meniscus Lesion [A] †	1/187 (0.53%)	1/178 (0.56%)	0/186 (0%)
Road Traffic Accident [A] *	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Spinal Compression Fracture [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Tendon Rupture [A] †	0/187 (0%)	0/178 (0%)	2/186 (1.08%)
Tibia Fracture [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Metabolism and nutrition disorders			
Dehydration [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Diabetes Mellitus Inadequate Control [A] †	1/187 (0.53%)	2/178 (1.12%)	1/186 (0.54%)
Hyperkalaemia [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Hypoglycaemia [A] †	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Hyponatraemia [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Musculoskeletal and connective tissue disorders			
Eagles Syndrome [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Foot Deformity [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Meniscal Degeneration [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Muscle Spasms [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Muscular Weakness [A] *	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Musculoskeletal Chest Pain [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Osteitis [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Osteoarthritis [A] *	2/187 (1.07%)	1/178 (0.56%)	1/186 (0.54%)
Patellofemoral Pain Syndrome [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Rhabdomyolysis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Spinal Column Stenosis [A] †	0/187 (0%)	2/178 (1.12%)	1/186 (0.54%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Gastric Neoplasm [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Bladder Cancer [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Breast Cancer [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Chronic Lymphocytic Leukaemia [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Colon Cancer [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Gastric Cancer [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Hepatic Neoplasm Malignant [A] †	0/187 (0%)	0/178 (0%)	2/186 (1.08%)
Leukaemia [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Lipoma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Lung Squamous Cell Carcinoma Metastatic [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Lung Squamous Cell Carcinoma Stage Unspecified [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Ovarian Cancer [A] †	1/77 (1.3%)	0/75 (0%)	0/70 (0%)
Prostate Cancer [A] †	1/111 (0.9%)	3/106 (2.83%)	1/115 (0.87%)
Transitional Cell Carcinoma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Nervous system disorders			
Altered State of Consciousness [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Benign Intracranial Hypertension [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Carotid Artery Stenosis [A] †	1/187 (0.53%)	0/178 (0%)	1/186 (0.54%)
Cerebral Infarction [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cerebral Ischaemia [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cerebrovascular Accident [A] †	1/187 (0.53%)	2/178 (1.12%)	3/186 (1.61%)
Cervical Myelopathy [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Coma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Convulsion [A] *	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Haemorrhage Intracranial [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Haemorrhagic Stroke [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Ischaemic Stroke [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Syncope [A] *	2/187 (1.07%)	2/178 (1.12%)	1/186 (0.54%)
Transient Ischaemic Attack [A] †	1/187 (0.53%)	1/178 (0.56%)	1/186 (0.54%)
VIIth Nerve Paralysis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Renal and urinary disorders			
Calculus Ureteric [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cystitis Haemorrhagic [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Diabetic Nephropathy [A] †	0/187 (0%)	2/178 (1.12%)	0/186 (0%)
Renal Failure [A] †	1/187 (0.53%)	1/178 (0.56%)	1/186 (0.54%)
Renal Failure Acute [A] †	2/187 (1.07%)	2/178 (1.12%)	2/186 (1.08%)
Renal Failure Chronic [A] †	0/187 (0%)	1/178 (0.56%)	3/186 (1.61%)
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia [A] †	1/111 (0.9%)	0/106 (0%)	0/115 (0%)
Epididymitis [A] †	1/111 (0.9%)	1/106 (0.94%)	0/115 (0%)
Uterine Haemorrhage [A] †	1/77 (1.3%)	0/75 (0%)	0/70 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Asthma [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Chronic Obstructive Pulmonary Disease [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Cough [A] *	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Dyspnoea [A] *	0/187 (0%)	0/178 (0%)	1/186 (0.54%)
Haemoptysis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Pleural Effusion [A] †	0/187 (0%)	2/178 (1.12%)	0/186 (0%)
Pulmonary Oedema [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Respiratory Distress [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Respiratory Failure [A] †	1/187 (0.53%)	1/178 (0.56%)	0/186 (0%)
Skin and subcutaneous tissue disorders			
Panniculitis [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Urticaria [A] *	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Social circumstances			
Victim of Homicide [A] *	1/187 (0.53%)	0/178 (0%)	0/186 (0%)
Vascular disorders			
Deep Vein Thrombosis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Extremity Necrosis [A] †	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Hypertension [A] †	2/187 (1.07%)	0/178 (0%)	0/186 (0%)
Hypotension [A] †	0/187 (0%)	1/178 (0.56%)	1/186 (0.54%)
Hypovolaemic Shock [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Malignant Hypertension [A] †	1/187 (0.53%)	0/178 (0%)	0/186 (0%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Temporal Arteritis [A] †	0/187 (0%)	1/178 (0.56%)	0/186 (0%)
Venous Insufficiency [A] †	0/187 (0%)	0/178 (0%)	1/186 (0.54%)

† 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	180/187 (96.26%)	172/178 (96.63%)	157/186 (84.41%)
Blood and lymphatic system disorders			
Anaemia [A] †	9/187 (4.81%)	10/178 (5.62%)	8/186 (4.3%)
Eye disorders			
Blepharitis [A] *	4/187 (2.14%)	3/178 (1.69%)	12/186 (6.45%)
Cataract [A] †	78/187 (41.71%)	65/178 (36.52%)	29/186 (15.59%)
Cataract Cortical [A] †	6/187 (3.21%)	11/178 (6.18%)	9/186 (4.84%)
Cataract Subcapsular [A] †	25/187 (13.37%)	22/178 (12.36%)	8/186 (4.3%)
Conjunctival Haemorrhage [A] †	39/187 (20.86%)	40/178 (22.47%)	28/186 (15.05%)
Conjunctival Hyperaemia [A] †	9/187 (4.81%)	12/178 (6.74%)	11/186 (5.91%)
Conjunctival Oedema [A] †	10/187 (5.35%)	10/178 (5.62%)	2/186 (1.08%)
Diabetic Retinal Oedema [A] †	24/187 (12.83%)	23/178 (12.92%)	18/186 (9.68%)
Diabetic Retinopathy [A] †	10/187 (5.35%)	14/178 (7.87%)	9/186 (4.84%)
Dry Eye [A] *	15/187 (8.02%)	10/178 (5.62%)	7/186 (3.76%)
Eye Pain [A] *	8/187 (4.28%)	13/178 (7.3%)	10/186 (5.38%)

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Lenticular Opacities [A] †	12/187 (6.42%)	6/178 (3.37%)	3/186 (1.61%)
Macular Fibrosis [A] †	21/187 (11.23%)	29/178 (16.29%)	12/186 (6.45%)
Macular Oedema [A] †	30/187 (16.04%)	27/178 (15.17%)	20/186 (10.75%)
Ocular Hypertension [A] †	19/187 (10.16%)	13/178 (7.3%)	6/186 (3.23%)
Punctate Keratitis [A] †	8/187 (4.28%)	9/178 (5.06%)	7/186 (3.76%)
Retinal Aneurysm [A] †	6/187 (3.21%)	9/178 (5.06%)	4/186 (2.15%)
Retinal Exudates [A] †	16/187 (8.56%)	12/178 (6.74%)	12/186 (6.45%)
Retinal Haemorrhage [A] †	11/187 (5.88%)	17/178 (9.55%)	9/186 (4.84%)
Retinal Neovascularisation [A] †	6/187 (3.21%)	16/178 (8.99%)	14/186 (7.53%)
Visual Acuity Reduced [A] *	27/187 (14.44%)	30/178 (16.85%)	12/186 (6.45%)
Vitreous Detachment [A] †	12/187 (6.42%)	14/178 (7.87%)	8/186 (4.3%)
Vitreous Haemorrhage [A] †	22/187 (11.76%)	32/178 (17.98%)	26/186 (13.98%)
General disorders			
Oedema Peripheral [A] *	9/187 (4.81%)	10/178 (5.62%)	6/186 (3.23%)
Infections and infestations			
Upper Respiratory Tract Infection [A] *	4/187 (2.14%)	13/178 (7.3%)	7/186 (3.76%)
Urinary Tract Infection [A] †	11/187 (5.88%)	8/178 (4.49%)	9/186 (4.84%)
Investigations			
Blood Creatinine Increased [A] †	9/187 (4.81%)	9/178 (5.06%)	8/186 (4.3%)
Intraocular Pressure Increased [A] †	50/187 (26.74%)	51/178 (28.65%)	15/186 (8.06%)
Metabolism and nutrition disorders			
Hypercholesterolaemia [A] †	10/187 (5.35%)	4/178 (2.25%)	6/186 (3.23%)
Vascular disorders			

	Dexamethasone 700 µg	Dexamethasone 350 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hypertension [A] †	35/187 (18.72%)	31/178 (17.42%)	15/186 (8.06%)

† 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.

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