



## Clinical trial results:

### Prevention of diabetic macular edema in patients with diabetic retinopathy treated with Ozurdex® after cataract surgery.

#### Summary

EudraCT number	2011-006063-22
Trial protocol	ES
Global end of trial date	03 November 2017

#### Results information

Result version number	v1 (current)
This version publication date	12 April 2024
First version publication date	12 April 2024
Summary attachment (see zip file)	Final report (INFORME FINAL OZURDEX-30 NOV 2018.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	FOM-ICI01-2011
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Fundación Oftalmológica del Mediterráneo
Sponsor organisation address	Avinguda Pio Baroja, 12, Valencia, Spain, 46015
Public contact	Marisa Barón, Fundación Oftalmológica del Mediterraneo, +34 96 278 76 20, baron_margar@gva.es
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Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 November 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 November 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Efficacy in reducing macular thickness at 6 months.

The evolution of macular thickness after cataract surgery will be compared with the use of Ozurdex® versus a control group without treatment at 6 months.

Protection of trial subjects:

The introduction of the phacoemulsification technique for cataract extraction (in which manages to reduce postoperative inflammation with respect to surgeries old as the extracapsular), good metabolic control by the patient and a good management of diabetic retinopathy prior to cataract surgery has achieved minimize this risk.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 June 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3

From 65 to 84 years	33
85 years and over	1

## Subject disposition

### Recruitment

Recruitment details:

The patients were recruited for 34 months (from 03Jun2014 to 27Apr2017).

Diabetic patients undergoing cataract surgery referred to FISABIO - Ophthalmology will be obtained Medical from regional hospitals without Retina Unit of

the Valencian Community and sent by the ophthalmologist of corresponding area of the Specialty Center of the Valencia.

### Pre-assignment

Screening details:

Patients diagnosed with type I or II diabetes mellitus. Patients with diabetic macular edema affecting the fovea with OCT thickness >250 microns. Non-proliferative and inactive diabetic retinopathy (without areas of ischemia on angiography). Visual acuity greater than 0.1 on the decimal scale (34 letters ETDRS). Cataracts with surgical indication.

### Pre-assignment period milestones

Number of subjects started	37
Number of subjects completed	33

### Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening failure: 4
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### Period 1

Period 1 title	OVERALL TRIAL (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
Arm title	Ozurdex® treatment group

Arm description:

50% of patients will be treated with intravitreal Ozurdex® implant after cataract surgery.

Arm type	Experimental
Investigational medicinal product name	Ozurdex®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intraocular instillation solution
Routes of administration	Intravitreal use

Dosage and administration details:

700 micrograms intravitreal implant in applicator after surgery of waterfalls

Arm title	Control group
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Arm description:

50% of patients will be only intervened in cataract surgery

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1[1]	Ozurdex® treatment group	Control group
Started	16	17
Completed	15	15
Not completed	1	2
Adverse event, serious fatal	1	-
Consent withdrawn by subject	-	2

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: There were 4 screening failures for not meeting some study criteria, before cataract surgery.

## Baseline characteristics

### Reporting groups

Reporting group title	Ozurdex® treatment group
Reporting group description: 50% of patients will be treated with intravitreal Ozurdex® implant after cataract surgery.	
Reporting group title	Control group
Reporting group description: 50% of patients will be only intervened in cataract surgery	

Reporting group values	Ozurdex® treatment group	Control group	Total
Number of subjects	16	17	33
Age categorical			
The median age among those treated with ozurdex is 74 years and the median age among those treated is 70 years.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	3	4
From 65-84 years	14	14	28
85 years and over	1	0	1
Age continuous			
Units: years			
median	74.0	70.0	
full range (min-max)	64.0 to 89.0	53.0 to 84.0	-
Gender categorical			
Units: Subjects			
Female	7	6	13
Male	9	11	20

## End points

### End points reporting groups

Reporting group title	Ozurdex® treatment group
Reporting group description: 50% of patients will be treated with intravitreal Ozurdex® implant after cataract surgery.	
Reporting group title	Control group
Reporting group description: 50% of patients will be only intervened in cataract surgery	

### Primary: Efficacy in reducing macular thickness at 6 months

End point title	Efficacy in reducing macular thickness at 6 months
End point description: The evolution of macular thickness after cataract surgery with the use of Ozurdex® will be compared versus the control group without treatment at 6 months.	
End point type	Primary
End point timeframe: 6 months	

End point values	Ozurdex® treatment group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: microns				
median (standard deviation)	311.1 (± 97.3)	334.6 (± 93.9)		

### Statistical analyses

Statistical analysis title	ATS test of the Brunner-Langer
Statistical analysis description: ATS test of the Brunner-Langer model on the homogeneity of evolution of both groups. Mann-Whitney (MW) test on homogeneity between groups at a given time.	
Comparison groups	Control group v Ozurdex® treatment group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.233
Method	Mann-Whitney

### Secondary: Impact on visual acuity

End point title	Impact on visual acuity
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End point description:

Compare the impact on visual acuity after cataract surgery with the use of Ozurdex® versus the control group

End point type	Secondary
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End point timeframe:

6 months

End point values	Ozurdex® treatment group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: number of letters				
median (standard deviation)	45.67 (± 8.69)	43.93 (± 9.80)		

## Statistical analyses

Statistical analysis title	ATS test of the Brunner-Langer model
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Statistical analysis description:

ATS test of the Brunner-Langer model on the homogeneity of evolution of both groups. Mann-Whitney (MW) test on homogeneity between groups at a given time.

Comparison groups	Ozurdex® treatment group v Control group
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Number of subjects included in analysis	30
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Analysis specification	Pre-specified
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Analysis type	
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P-value	= 0.744
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Method	Mann-Whitney
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## Secondary: Impact on intraocular pressure

End point title	Impact on intraocular pressure
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End point description:

Compare the impact on intraocular pressure after cataract surgery with the use of Ozurdex® versus the control group.

End point type	Secondary
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End point timeframe:

6 months



End point values	Ozurdex® treatment group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: mmHg				
median (standard deviation)	15.5 (± 2.2)	16.5 (± 2.5)		

## Statistical analyses

Statistical analysis title	ATS test of the Brunner-Langer model
Statistical analysis description:	
ATS test of the Brunner-Langer model on the homogeneity of evolution of both groups. Mann-Whitney (MW) test on homogeneity between groups at a given time.	
Comparison groups	Ozurdex® treatment group v Control group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.325
Method	Mann-Whitney

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

No adverse effect or serious adverse effect were recorded throughout the development of the trial.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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### Reporting groups

Reporting group title	Control group
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Reporting group description: -

Reporting group title	Ozurdex treatment group
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Reporting group description: -

Serious adverse events	Control group	Ozurdex treatment group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Control group	Ozurdex treatment group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 15 (46.67%)	4 / 15 (26.67%)	
Cardiac disorders			
Heart failure			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	0	
Eye disorders			
Increase ocular pressure	Additional description: One patient had an increase the ocular pressure		
subjects affected / exposed	7 / 15 (46.67%)	4 / 15 (26.67%)	
occurrences (all)	0	0	
Posterior vitreous detachment			

subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 0	0 / 15 (0.00%) 0	
Worsening macular edema	Additional description: These patients required treatment with ozurdex.		
subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 0	0 / 15 (0.00%) 0	
Incipient membrane	Additional description: One patient developed an incipient membrane		
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 0	
Discomfort due to dystischiasis			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 0	
Respiratory, thoracic and mediastinal disorders			
A cold	Additional description: One patient had a cold		
alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 0	0 / 15 (0.00%) 0	
Respiratory insufficiency	Additional description: One patient had a respiratory insufficiency		
alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 0	0 / 15 (0.00%) 0	
Renal and urinary disorders			
Urinary infection			
alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported