

SUMMARY

Invent ZO is now called CT ASPHINA 604P

Sponsor : IOLTECH S.A., A company of Carl Zeiss Meditec AG	Reference protocol : 331 D301-06	Investigator- Coordinator : Dr Damien Gatinel
Product name : project 331 Aspheric intraocular lens	Number of centres : 3	Monitor :
Name of the medical device: INVENT ZO	Countries : France – Italy – Germany	
Title of the trial: Efficacy and tolerance of a new aspheric Intraocular Lens		
DEVELOPMENT PHASE: phase III		
METHODOLOGY : multi centre, open trial, comparison with standard values		
INVESTIGATOR-COORDINATOR : Dr Damien Gatinel		
OBJECTIVES :		
<ul style="list-style-type: none">• Main objective: to evaluate the performance of the 331 aspheric IOL in terms visual quality assessed by MTF measurement• Secondary objectives : assessment of<ul style="list-style-type: none">○ Other performance criteria: visual acuity, contrast sensitivity○ local safety : stability of the IOL positioning (centration, tilt, ..), PCO, IOP○ general safety : adverse events		
NUMBER OF PATIENTS : 60 patients requiring cataract surgery (3 centres - 20 patients per centre)		
INVESTIGATIONAL DEVICE : Aspheric intraocular lens Capsular intraocular lens with an aspheric optic, made of hydrophilic acrylic (model 331 L), indicated after surgical removal of a cataract – CE mark 0459		
DURATION OF TREATMENT: the intraocular lens, indicated after surgical removal of cataract, has estimated life duration of 15 years (after implantation).		
DURATION OF FOLLOW-UP FOR EACH PATIENT: 12 months		
MAIN INCLUSION CRITERIA: routine cataract, uncomplicated cataract surgery, capsular bag implantation of the IOL		
MAIN EXCLUSION CRITERIA: uveitis, diabetes, glaucoma, pseudo-exfoliation syndrome, pathologic myosis, retinitis pigmentosa, keratoconus, high myopia (<-6D), high hyperopia (>+4D), high astigmatism (>1.5D)		
EXPERIMENTAL PLAN: Number of visits – main criteria for each		
<ul style="list-style-type: none">• one (1) inclusion visit (between D -90 and D -1) in order to check inclusion criteria, to carry out a complete ophthalmological examination, to measure the baseline values of the evaluation criteria of efficacy and safety• one (1) surgery for implantation of the IOL (D0)• three (3) post operative follow-up visits : M1, M6 and M12 for assessment of MTF (2 pupil diameters), visual acuity, refraction, contrast sensitivity (1 centre, M1 only), glare, halos, PCO, IOL centration, IOP		

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EVALUATION CRITERIA Efficacy : <ul style="list-style-type: none"> – Measurement of High Order Aberration components of the whole eye MTF (Modulation Transfer Function) for 2 pupil diameters (3 mm and 5 mm). – Visual acuity recovery (far and near, uncorrected and best corrected visual acuity) – Refraction – Contrast sensitivity (1 centre, M1 only). Tolerance : <ul style="list-style-type: none"> – Evaluation of IOL position (centration, tilt) – Evaluation of visual symptoms (glare, halos, blurring, other), – Posterior chamber opacification (PCO) – Intraocular pressure (IOP) – General safety using follow-up of possible occurring adverse event. 		
STATISTICAL METHODS : Statistical analysis: The analysis will be mostly descriptive: <ul style="list-style-type: none"> ✓ Quantitative endpoints will be presented in terms of mean, standard deviation, median, extreme values, 95% confidence interval, number of patients and missing data. ✓ Qualitative endpoints will be presented in terms of number and percentage of each modality and the number of missing data. For the primary efficacy endpoint, the visual quality assessed by MTF measurement will consist on the analysis of the area ratio (which measures the deviation of the MTF curve of the patient from the MTF curve corresponding to a “perfect” theoretical optical system). The mean value of the area ratio will be calculated within each group (study group and control group) and the confidence intervals will be compared in order to evaluate the performance of the 331 aspheric IOL compared to young eyes Three analyses will be conducted after one month, six months and 12 months post-surgery. The analysis will be computed with SAS Version 9.1.3 (Copyright (c) 2002-2003 by SAS Institute Inc., Cary, NC, USA.). Comparison with reference population: MTF measurements performed in patients participating in the trial will be compared with measurement of the MTF for 2 pupil diameters from 60 young people.		

FLOW-CHART

Visits	Inclusion	Surgery	visit 1	visit 2	visit 3
Days	D-90 to D-1	D0	M1	M6	M12
Informed consent	X				
Demographic data	X				
Medical history	X				
Ophthalmologic examination	X				
Associated pathology	X		X	X	X
Concomitant treatment	X		X	X	X
Keratometry	X				
Axial length	X				
Anterior chamber depth	X				
IOL Implantation		X			
MTF measurement pupil Ø 3mm			X	X	X
MTF measurement pupil Ø 5mm			X	X	X
Near and distance UCVA	X		X	X	X
Near and distance BCVA	X		X	X	X
Refraction	X		X	X	X
Vision disturbances (glare, halos, blurring)	X		X	X	X
IOL position		X	X	X	X
PCO				X	X
IOP	X		X	X	X
General safety: Adverse events		X	X	X	X