

SUMMARY

Note: XL Stabi ZO is now called CT ASPHINA 603P

XL Stabi Sky is now called CT SPHERIS 203P

Sponsor: Carl Zeiss Meditec SAS	Reference protocol: 347 D301/07	Investigator- Coordinator: Prof. Günther Grabner
Product name: project 347 ZO optic	Number of centre : 1	Monitor: ASCOPharm
Name of the medical device: XL Stabi ZO and XL Stabi Sky	Country: Austria	
Title of the trial: Efficacy and tolerance of a new aspheric intraocular lens. Comparison with the spherical counterpart.		
DEVELOPMENT PHASE: IV		
METHODOLOGY: mono-centric, randomized-controlled, evaluator and patient blinded clinical trial – pilot study		
INVESTIGATOR-COORDINATOR: Prof. Günther Grabner		
OBJECTIVES:		
<ul style="list-style-type: none"> • Main objective: to evaluate the performance of the XL Stabi ZO aspheric IOL in terms of visual quality assessed by MTF measurement vs XL Stabi Sky spherical IOL • Secondary objectives: assessment of <ul style="list-style-type: none"> ○ contrast sensitivity ○ depth of field ○ reading acuity, reading speed and reading distance ○ keratometry ○ refraction stability ○ local safety: stability of the IOL positioning (centration, tilt, postoperative “ACD”, ...), PCO, IOP, ECC ○ general safety: adverse events 		
NUMBER OF PATIENTS: 40 patients requiring cataract surgery (20 patients per treatment group). Only one eye of each patient will be followed-up in the framework of the study. Allocation of treatment group (XL Stabi Sky or XL Stabi ZO) will be randomized.		
INVESTIGATIONAL DEVICE:		
XL Stabi ZO Aspheric intraocular lens: Capsular intraocular lens with an aspheric optic, made of hydrophilic acrylic, indicated after surgical removal of a cataract – CE mark 0459		
XL Stabi Sky Spherical intraocular lens: Capsular intraocular lens with a spherical optic, made of hydrophilic acrylic, indicated after surgical removal of a cataract – CE mark 0459		
Both lenses have the same platform.		
The range of power available for both IOL models will be from 18 to 25 by 0.5D step, to 26 by 1D step.		
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, pupil diameter not lower than 4.5mm in mesopic condition without pharmacological dilatation, axial length between 22 and 25mm.		
MAIN EXCLUSION CRITERIA: uveitis, acute ocular disease or external/internal infection, diabetes with retinal changes, glaucoma, pseudo-exfoliation syndrome, pathologic miosis, retinitis pigmentosa, keratoconus, high myopia (<-6D), high hyperopia (>+4D), high corneal astigmatism (>1.5D)		

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<p>EXPERIMENTAL PLAN: Number of visits – main criteria for each</p> <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 ophthalmologic 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, M3 and M12 for assessment of MTF, visual acuity, refraction, contrast sensitivity, keratometry, reading performance, depth of field, visual symptoms, PCO, IOL centration, IOP, ECC, corneal topography 		
<p>Efficacy:</p> <ul style="list-style-type: none"> – assessment of High Order Aberration components and spherical aberration Z(4,0) of the whole eye – MTF (Modulation Transfer Function) for 2 pupil diameters (3 mm and 4.5 mm) using the WASCA aberrometer (Carl Zeiss): average MTF (mean of tangential and sagittal MTF) for spherical aberrations and high order aberrations, and total amount of spherical aberration of the whole eye – Visual acuity recovery (far and near, uncorrected and best corrected visual acuity) – Refraction using autorefractometer (KR 7000P, Topcon) – Contrast sensitivity in photopic and mesopic conditions, with and without glare – Depth of field using defocus curve – Reading acuity, reading speed and subjectively convenient reading distance using the “Salzburg Reading Desk” – Keratometry <p>Tolerance:</p> <ul style="list-style-type: none"> – Evaluation of IOL position <ul style="list-style-type: none"> ○ Centration ○ Tilt ○ Postoperative “ACD” – Evaluation of visual symptoms (glare, halos, blurring, other) – Posterior chamber opacification (PCO) – Intraocular pressure (IOP) – Endothelial cell count – Corneal topography – General safety using follow-up of possible occurring adverse event. 		

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<p>STATISTICAL METHODS:</p> <p>NB: patients presenting an IOL visible decentration associated with a pupil diameter higher than 6 mm will be excluded from the MTF analysis of the concerned visit.</p> <p>Statistical analysis:</p> <p>All relevant data will be summarized this way :</p> <ul style="list-style-type: none"> -Quantitative endpoints will be presented in terms of mean, standard deviation, median, Q1, Q3, extreme values, 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. <p>To determine comparability of the 2 treatment groups and the success of the randomisation procedure, baseline characteristics of the patients according to the treatment group will be compared.</p> <p>The main criterion is assessed by MTF measurement.</p> <p>The mean value of the MTF will be calculated within the 2 treatment groups, for each spatial frequency, from 0 to 80 cycles/degree, by step of 5, and compare with the non-parametric test of Wilcoxon.</p> <p>The secondary efficacy endpoints of this study, if they are continuous, Wilcoxon tests will be conducted at 5% level of significance.</p> <p>If they are categorical parameters, Chi-squared test will be used.</p>		