

Cover Page

Study Protocol

Project title: Genetic and risk factors in exfoliation glaucoma (Glaugene)

NCT: N.A.

Date of approval: 2012, May 6.

Summary and variable explanations

Project: Genetic and risk factors in exfoliation glaucoma (Glaugene)

Variables at inclusion:

- 1) Age: measured in years
- 2) Sex: female/male
- 3) Visual acuity: measured in Snellen's units (0.1-1.0)
- 4) Intraocular pressure (IOP): measured in mmHg, measured with applanation tonometer.
- 5) Central corneal thickness (CCT): measured with OCT, measured in μm
- 6) Visual field: performed using a Humphrey device, software 24-2 (SITA-fast). The variables included in the study are the mean deviation (MD) and the visual field index (VFI). The MD measured in dB, and the VFI measured in %.
- 7) Gonioscopy: performed in dark rum, classified the angle in 4-0 and pigmentation in 3-0.
- 8) The cup/disc ratio (CD ratio), measured with a 90-lins after dilation.
- 9) Cataract status measured as patient cataract operated or not (Yes/No).
- 10) Presence of glaucoma in one or both eyes.
- 11) Presence of exfoliation, measured after dilation. Classified as Yes/No.
- 12) Treatment with IOP lowering eye-drops: measured as the number of medicines and not the number of bottles.
- 13) Laser (SLT) treatment: measured as Yes/No.
- 14) At inclusion patients answered a questionnaire with several questions like how long they had glaucoma, diabetes, hypertension, smoking, family history for glaucoma, use of medicines, other eye diseases and other general diseases. Please see the questionnaire in a separate file.
- 15) Genetics were evaluated as allele's frequencies of the *LOXL1*_SNPs. Genetic analysis was performed at LGC Genomics (Hoddesdon, Herts, UK) using competitive allele-specific PCR (KASP) genotyping.

Variables at follow-up (three years) tested every six months:

- 1) Visual acuity: as above, see 3)
- 2) The IOP: as above see 4)
- 3) The visual field (MD and VFI), as above see 6)
- 4) Cataract operation: as above, see 9)
- 5) Number of medications: as above, see 12)
- 6) Laser treatment (SLT), as above, see 13)

Study Protocol

Inclusion

Patients' ID:

Protocol number:

Name and surname:

Date:

Age:

Sex:

	Right	Left
Visual acuity		
IOP		
CCT		
VF-MD		
VF-VFI		
Gonioscopy-angle		
Gonioscopy-pigment		
C/D Ratio		
Cataract operation		
Glaucoma		
Exfoliation		
Eye-drops		
SLT		

Additional information:

6 months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information:

12 Months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information:

18 Months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information:

24 Months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information:

30 Months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information:

36 Months Check-up

	Right	Left
Visual acuity		
IOP		
Visual field-MD		
Visual-field-VFI		
Cataract operation		
Number of medications		
SLT		

Additional information: