Voortzetting Follow-Up Imaging Onderzoek bij Glaucoom en Oculaire Hypertensie.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20750

Source
NTR

Brief title
N/A

Health condition

1. Glaucoma;

2. Ocular hypertension.

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Schiedamsevest 180
3011 BH Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Intervention

Outcome measures

Primary outcome

Sensitivity and specificity of glaucoma diagnostics (i.e. for glaucoma detection and for glaucoma progression detection).

Secondary outcome

N/A

Study description

Background summary

Rationale:

Glaucoma is the second leading cause of blindness in the world. Since glaucoma causes thinning of the nerve fiber layer prior to loss of vision, early detection may allow early treatment and, thus, prevent permanent loss of vision.

Objective:

Improving diagnostics for early detecting of (progression of) glaucoma.

Study design:

Longitudinal cohort.

Study population:

Glaucoma and ocular hypertension patients.

Intervention:

Hypotensive therapy.

Main study parameters/endpoints:

Sensitivity and specificity of glaucoma diagnostics.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no anticipated major side effects associated with any of these measurements. The overall level of risk is similar to that of a full eye examination in a doctor's office. Burden is considered to be low.

Study objective

Structural imaging is more sensitive to early (progression) detection than functional measurements (i.e. visual fields).

Study design

Control visits as usual.

Intervention

Glaucoma group: careful follow-up with visual fields and structural imaging; no experimental intervention (care as usual).
Ocular hypertension groups: 3 arms (timolol, betaxolol and placebo eye drops), masked, randomized, prospective, placebo-controlled; careful follow-up with visual fields and structural imaging.

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;

2. Glaucoma;

3. Ocular hypertension.

Exclusion criteria

1. Ocular opacifications (eg. of the cornea, lens etc.);

2. Nystagmus;

3. Significant other eye disorders (eg. age-related macular degeneration, other than mild cataract);

4. Systemic disease possibly affecting the eye (eg. systemic hypertension, diabetes);

5. Refractive errors larger than 10 D myopia or 5 D hyperopia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2000
Enrollment:	685
Type:	Actual

Ethics review

Positive opinion

Date:	10-01-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1152
NTR-old	NTR1195
Other	Oogziekenhuis Rotterdam, Schiedamsevest 180, 3011 BH Rotterdam : OZR-2000-06-II
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

1. Reus NJ, Lemij HG. Relationships between Standard Automated Perimetry, HRT Confocal Scanning Laser Ophthalmoscopy, and GDx VCC Scanning Laser Polarimetry. Invest Ophthalmol Vis Sci. 2005;46(11):4182-8;

2. Colen ThP, NEML Tang, PGH Mulder, HG Lemij. Sensitivity and specificity of new GDx parameters. Journal of Glaucoma 2004;13(1):28-33;

3. Reus NJ, HG Lemij. The relationship between standard automated perimetry and GDx VCC measurements. Investigative Ophthalmology & Visual Science 2004;45(3):840-845;

4. Reus NJ, HG Lemij. Diagnostic accuracy of the GDx VCC for glaucoma. Ophthalmology 2004;111(10):1860-1865;

5. Reus NJ, HG Lemij. Scanning laser polarimetry of the retinal nerve fiber layer in perimetrically unaffected eyes of glaucoma patiënts. Ophthalmology 2004;111(12):2199-2203;

6. Tannenbaum DP, D Hoffman, HG Lemij, DF Garway-Heath, DS Greenfield, J Caprioli. Variable corneal compensation improves discrimination between normal and glaucomatous eyes with the scanning laser polarimeter. Ophthalmology 2004;111(2):259-264;

7. Colen TP, HG Lemij. Sensitivity and specifity of the GDx: clinical judgment of standard printouts versus the number. Journal of Glaucoma 2003;12(2):129-133;

8. Reus NJ, TP Colen, HG Lemij. Visualization of localized retinal nerve fiber layer defects with the GDx with individualized and with fixed compensation of anterior segment birefringence. Ophthalmology 2003;110(8):1512-1516;

9. Vermeer KA, Vos FM, Lemij HG, Vossepoel AM.`Detecting glaucomatous wedge shaped defects in polarimetric images. Med Image Anal. 2003;7(4):503-511.

Burr JM, Botello-Pinzon P, Takwoingi Y, Hernández R, Vazquez-Montes

M, Elders A, Asaoka R, Banister K, van der Schoot J, Fraser C, King

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synthesis and economic evaluation. Health Technol Assess. 2012;

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Bryan SR, Vermeer KA, Eilers PH, Lemij HG, Lesaffre EM. Robust and Censored Modeling and Prediction of Progression in Glaucomatous Visual Fields. Invest Ophthalmol Vis Sci. 2013; 54(10): 6694-6700. PMID: 24030462