Collection of Normative and Glaucoma Data Using GDx VCC Scanning Laser Polarimetry

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To obtain clinical data from normal individuals to establish significance limits for the GDx RNFL measurements using the ECC method and to collect GDx RNFL measurements in subjects with early, moderate and advanced glaucoma using the ECC method to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON30646

Source
ToetsingOnline

Brief title
Normative and Glaucoma Data Using GDx VCC

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma, increased intraocular pressure

Research involving
Human

Sponsors and support

Primary sponsor: Carl Zeiss Meditec, Inc.
Source(s) of monetary or material Support: Carl Zeiss Meditec;Inc.;5160 Hacienda Drive;Dublin;CA 94568

Intervention

Keyword: Glaucoma, Nerve Fiber Indicator, Normative data, Scanning Laser Polarimetry

Outcome measures

Primary outcome

Normative limits for GDx parameters (protocol, p 17-18), and Thickness Map. GDx parameters (protocol, p 18) are going to be used to train NFI.

Secondary outcome

1 Accuracy of the NFI in classifying glaucoma and non-glaucoma subjects.

2 To compare the GDx RNFL measurements obtained using the ECC method and the standard imaging method (VCC) in normal and glaucoma subjects.

3 To optimize the screening exam protocol and to determine the specificity and the sensitivity of the screening protocol for glaucoma.

Study description

Background summary

An objective method to assess the retinal nerve fiber layer (RNFL) is through scanning laser polarimetry (SLP). To improve the ability of SLP to detect small changes at low retardance, a new enhanced imaging method, enhanced corneal compensation (ECC), with improved signal/noise ratio has been developed for RNFL measurements with GDx. This method employs modified software used during imaging but is otherwise identical to the original hardware.

Study objective

To obtain clinical data from normal individuals to establish significance limits for the GDx RNFL measurements using the ECC method and to collect GDx RNFL measurements in subjects with early, moderate and advanced glaucoma using

the ECC method to train a machine learning classifier, the Nerve Fiber Indicator (NFI).

Study design

This is an open-label, prospective, multicenter study. After undergoing a general ophthalmic examination, qualifying subjects will undergo scans of their retinal nerve fiber layers with the GDx. This study is designed in a way to support a longitudinal data collection if the PIs or the Study Sponsor decide to reconsent the same subjects for further longitudinal data collection.

Study burden and risks

For the purpose of this study, normal and glaucoma subjects are required. Burden is considered to be limited, risk is similar to that of a full eye examination in a doctor's office. Participants do not benefit from this study (45 Euro excepted).

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Normal subjects:
1 Males or females of legal age.
2 Able and willing to make the required study visits.
3 Able and willing to give consent and follow study instructions.
4 Must have a normal visual field in both eyes. ;Glaucoma subjects:
1 Males or females of legal age.
2 Able and willing to make the required study visits.
3 Able and willing to give consent and follow study instructions.
4 Must have glaucoma diagnosis.
5 Must have a glaucomatous visual field abnormality in either eye.

Exclusion criteria

Normal subjects:
(Ophthalmic:)
1 Best corrected visual acuity in either eye worse than 20/40 on a Snellen or on a Snellen equivalent acuity chart.
2 Refractive error outside -10.00D to +5.00D range.
3 Glaucoma in either eye.
4 Ocular hypertension (IOP > 22 mm Hg) in either eye.
5 History of ocular hypertension in either eye.
6 Occludable angle with iridolenticular contact or evidence of iridolenticular contact or peripheral anterior synechia.
7 History of angle closure glaucoma in either eye.
8 Presence of disc hemorrhage.
9 Previous cataract surgery in either eye.
10 Previous laser trabeculoplasty in either eye.
11 Previous refractive or vitreoretinal surgery in either eye.
12 Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo-retinal disease in either eye upon dilated examination, or upon evaluation of retinal photos.
(Systemic:)
13 History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia and multiple sclerosis.
14 A life threatening and debilitating disease.
15 Participation in any study involving a non-FDA approved investigational drug (IND) within the past month, or ongoing participation in a study with a non-FDA approved investigational

device (IDE).
16 Current or recent (within the past 14 days) use of an agent with photosensitizing properties by any route (e.g., Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.).
17 Concomittant use of hydrochloroquine and chloroquine.;Glaucoma subjects:
(Ophthalmic:)
1 Best corrected visual acuity in either eye worse than 20/40 on a Snellen or on a Snellen equivalent acuity chart.
2 Refractive error outside -10.00D to +5.00D range.
3 Secondary glaucomas except pigmentary and pseudoexfoliation glaucoma.
4 Evidence of a VF abnormality which is consistent with a disease other than glaucoma.
5 Previous cataract surgery in the study eye.
6 Previous refractive or vitreoretinal surgery in the study eye.
7 Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo-retinal disease in either eye upon dilated examination or upon evaluation of retinal photos.
(Systemic:)
8 History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia and multiple sclerosis.
9 A life threatening and debilitating disease.
10 Participation in any study involving a non-FDA approved investigational drug (IND) within the past month, or ongoing participation in a study with a non-FDA approved investigational device (IDE).
11 Current or recent (within the past 14 days) use of an agent with photosensitizing properties by any route (e.g., Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.).
12 Concomitant use of hydrochloroquine and chloroquine.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2007

Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	30-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL13416.078.06