Comparing test-retest variability of Compass perimetry with the Humphrey Field Analyzer at the edges of glaucomatous scotomas

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To determine the test-retest variability of Compass perimetry at the edges of glaucomatous scotomas and compare it with the Humphrey Field Analyzer.

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

Summary

ID

NL-OMON48106

Source
ToetsingOnline

Brief title
Test-retest variability of Compass versus HFA

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Blindenbelangen

Intervention

Keyword: Compass perimetry, Glaucoma, Humphrey Field Analyzer, Variability of measurements

Outcome measures

Primary outcome

Test-retest variability of visual field locations surrounding scotoma borders.

Secondary outcome

N.a.

Study description

Background summary

Early and accurate detection of progression is essential for preventing further irreversible visual field loss in the glaucoma patient. Visual field loss is most commonly tested with the Humphrey Field Analyzer (HFA). However, the HFA shows high measurement variability, notably at the borders of scotomas, making it difficult to determine if a scotoma is stable or shows progression. This variability may in part be due to gaze instability. By using an eye tracker that can compensate for this gaze instability, the Compass fundus perimeter (CMP) could lower the variability at scotoma borders. However, the test-retest variability at the edges of scotomas with the CMP has not yet been explored.

Study objective

To determine the test-retest variability of Compass perimetry at the edges of glaucomatous scotomas and compare it with the Humphrey Field Analyzer.

Study design

Prospective cross-sectional study.

Study burden and risks

Visual field testing with the HFA is part of usual care. Each patient will undergo 2 study visits. Each study visit an examination with the Compass perimeter and an examination with the HFA perimeter, using the standard 24-2

test pattern, will be performed. Added burden will be 3 hours in total for each patient. Risks are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Glaucoma
Age 40 to 80 years
Vision 0.3 logMar of better
3 or more reliable HFA tests in last 5 years

Exclusion criteria

Ocular surgery (uncomplicated cataract surgery and/or glaucoma surgery in either eye performed more than 6 months ago excepted)
Ocular pathology other than glaucoma that can affect the visual field

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Compass perimeter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-10-2019
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	NL70770.078.19