# Evaluating new perimetric techniques in the elderly.

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

## Summary

### ID

NL-OMON45417

**Source**
ToetsingOnline

**Brief title**
Evaluating new perimetric techniques in the elderly.

### Condition

- Glaucoma and ocular hypertension

**Synonym**
Glaucoma; POAG

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W,European committee; Uitzicht

## Intervention

**Keyword:** Diagnostics, Elderly, Glaucoma, Visual perimetry

## Outcome measures

### Primary outcome

The output of each perimetric device and of the feedback questionnaire.

### Secondary outcome

N/A

# Study description

### Background summary

Glaucoma is a progressive optical neuropathy that affects older adults, and it is one of the main causes of irreversible blindness if not treated. Standard Automatic Perimetry (SAP) is the most common visual field technique used to diagnose and monitor the progression of pathology, but in older patients it has some limitations. Firstly, normative data is missing in elderly patients - most databases contain only patients up to 70 years. Secondly, although some patients experience a normal cognitive decline due to age, it is often the case that more serious motor and/or cognitive disorders also occur. For these two reasons, we need (1) normative data for older people and (2) devices that are more user-friendly than current technologies. In this study we will compare five new field field measurements with the gold standard. Then we collect normative data for the best two tests, which are accordingly chosen for their user-friendliness and distinctiveness.

### Study objective

The first aim of this study is to evaluate a number of new perimetric methods regarding their ability to detect glaucomatous visual field defects without being stressful or difficult for older participants. In this first study, both controls and glaucoma patients will undergo a neuropsychological screening test to exclude any cognitive impairment. We determine for each new technique (1) whether the test score differs between the glaucoma patients and the controls and (2) the user-friendliness. For the latter, we use a feedback questionnaire. Hereafter we select the tests that meet both of the above requirements (distinctiveness and user-friendliness) and we use these to collect and apply normative data in 100 healthy subjects to 100 glaucoma patients. This allows us

to determine the sensitivity at a fixed specificity of 95%, a common value in glaucoma care. In a follow-up study that is not included in this application, we will apply the selected devices to older people with cognitive and/or motor conditions.

### Study design

Observational cross-section study

### Study burden and risks

Glaucoma patients and healthy subjects will have to visit the ophthalmology department to perform the screening tests, and, if selected, the visual field tests selected for the experiment. Healthy subjects will undergo a routine ophthalmic screening test to rule out the presence of glaucoma. Glaucoma patients will not perform any ophthalmic screening, therefore there is no risk of identifying any other eye conditions. Both glaucoma patients and healthy subjects will then undergo a neuropsychological screening test to rule out the presence of any pathological cognitive impairment. If any abnormal screening results are obtained in any of the two screenings, they will be referred to their GP. Detection of signs of an eye condition or cognitive deficit may cause psychological stress, however, an early diagnosis will allow treatments to be initiated and therefore more preservation of visual or cognitive functioning. Participants who meet the selection criteria will then undergo the selected battery of visual field tests. Patients and healthy subjects will spend 21.5 hours and 2.5 hours in our lab, respectively, to complete the required tasks. Subjects with glaucoma will be recruited from a population of glaucoma patients who visit the ophthalmology clinic at the UMCG. For the recruitment of healthy subjects, we will invite the spouses of the patients and will place poster adverts in and around the UMCG.

## 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

70-95 years of age
Written informed consent
For healthy subjects: questionnaire results that do not indicate the presence of any ophthalmic abnormality, no cognitive impairment detected in the MoCA
For glaucoma patients: diagnosed glaucoma, no cognitive impairment in the MoCA

## Exclusion criteria

For healthy subjects: MoCA score below 26; any eye disease/visual field loss; intraocular pressure above 21 mmHg; family history of glaucoma.
For glaucoma patients: MoCA score below 26; non-glaucomatous visual field loss.

# Study design

## Design

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| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

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| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-03-2018 |
| Enrollment: | 250 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 25-10-2017 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL60939.042.17 |
| Other | UMCG register 201700338 |