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# Clinical performance of Compass in the diagnosis of glaucoma

**Submission date**
31/07/2015

**Recruitment status**
No longer recruiting

**Registration date**
20/08/2015

**Overall study status**
Completed

**Last Edited**
12/09/2023

**Condition category**
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Glaucoma is an eye condition which develops when a fluid inside the eye (called aqueous humour) cannot drain properly, causing pressure to build up that can result in damage to the optic nerve and nerve fibres from the retina. It often affects both eyes, generally with one being more affected than the other, and, over time, it can lead to a partial or complete loss of sight. The purpose of this study is to test the diagnostic performance of COMPASS, a new device for assessing the degree of glaucoma in comparison with the Humphrey HFA-II perimeter, which is the recognized clinical "gold standard". In particular this study is aimed at comparing reproducibility of the test results, detection and staging (i.e. assessing how severe it is) of glaucoma, and how long the test takes. The study also aims to obtain reference values from a group of healthy people without glaucoma.

Who can participate?
Healthy volunteers and glaucoma patients aged 18-90.

What does the study involve?
All participants have a complete ophthalmological evaluation to see whether they are eligible to take part. Participants that are eligible either has one perimetric test in both eyes with the Humphrey and COMPASS or a total of 6 tests with the two perimeters to assess test-retest variability (i.e. to see whether the test comes up with a similar result every time).

What are the possible benefits and risks of participating?
No specific benefits for participants are expected. There are no known risks associated with taking part in the study. No adverse events have been reported from a previous study with the Compass device except for lacrimation (eye watering).

Where is the study run from?
1.Ophthalmology Hospital San Paolo in Milan (Italy)
2.Hospital Santa Maria della Misericordia in Udine (Italy)
3.Moorfields Eye Hospital, London (UK)
4.University of Iowa, Carver College of Medicine (USA)
5.University of Melbourne Eyecare, Department of Optometry & Vision Sciences (Australia)

6.IRCCS - Foundation "Bietti GB" for the Study and Research in Ophthalmology ONLUS (Italy)
7.Ophthalmology Clinic of the Sant'Andrea Hospital of Rome (Italy)

When is the study starting and how long is it expected to run for?
September 2015 to July 2017

Who is funding the study?
CenterVue Spa (Italy)

Who is the main contact?
Miss Chiara Rui

# Contact information

### Type(s)
Public

### Contact name
Miss Chiara Rui

### Contact details
Via San Marco 9H
Padova
Italy
35129

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CMP_002

# Study information

### Scientific Title
Clinical performance of Compass in the diagnosis of glaucoma: a comparison with Humphrey HFA.

### Study objectives
The aim of the study is to evaluate the diagnostic performance of a new perimeter (the "Compass") and compare it to the Humphrey HFA on a population of normal subjects and glaucomatous patients in order to:
1. Compare test-retest variability
2. Compare clinically performance in staging glaucoma
3. Compare test time

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
International Ethics Committee of Milan, Zone A, 22/07/2015, ref: Prot. n° 0019459

## Study design
Observational multicentric cross sectional trial

## Primary study design
Observational

## Secondary study design
Cross sectional study

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Glaucoma

## Interventions
This cross-sectional, observational, multi-centric study involves acquisition of visual field tests from both normal and glaucomatous subjects using two different perimeters. Each patient enrolled undergoes a full ophthalmological evaluation and perimetric tests on both eyes or on one randomly selected eye, depending on study arm. One arm is aimed at assessing test-retest variability, the other one at comparing visual field values of both perimeters. Both arms include healthy and glaucomatous subjects.

## Intervention Type
Other

## Primary outcome measure
Test-retest variability, assessed by parametric statistical methods, on both normal subjects and subjects with glaucoma.

## Secondary outcome measures
1. Sensitivity / specificity of the diagnosis of glaucoma using both perimeters vs. diagnosis from a glaucoma expert using independent data (morphological and functional data)
2. Average test time
3. Age-matched normative database

## Overall study start date

14/09/2014

### Completion date
31/07/2017

# Eligibility

### Key inclusion criteria
Normal subjects:
1. Age: 18 - 90 years old
2. best corrected visual acuity > 0.8 (if <50 years old) or >6/10 (if >50 years old) in study eye
3. Refraction -10D / +6D; astigmatism between - 2D and 2D
4. Normal optic nerve head in both eyes (no evidence of excavation, rim thinning, notching, disc hemorrhages, RNFL thinning);
5. IOP less than 21 mmHg in both eyes
6. No ocular pathologies, trauma, surgeries (apart from uncomplicated cataract surgery) in both eyes
7. Absence of pathologies that can affect visual field
8. No use of drugs interfering with the correct execution of perimetry
9. Should have at least two reliable VF exams (for example one HFA, one Compass)

Glaucoma patients:
1. Age: 18 - 90 years old
2. Best corrected visual acuity > 0.8 (if <50 years old) or >6/10 (if >50 years old) in study eye;
3. Refraction -10D / +6D; astigmatism between - 2D and 2D
4. Glaucomatous optic nerve head in both eyes (according to the specialist opinion at ophthalmoscopy) and abnormal OCT (ONH and RNFL)
5. Patients under anti-glaucoma therapy
6. No ocular pathologies, trauma, surgeries (apart from uncomplicated cataract surgery) in both eyes
7. Absence of pathologies that can affect visual field other than glaucoma
8. No use of drugs interfering with the correct execution of perimetry or that would produce visual field loss
9. Should have at least two reliable VF exams (for example one HFA, one Compass)

### Participant type(s)
Mixed

### Age group
Mixed

### Sex
Both

### Target number of participants
at least 1200 patients

### Total final enrolment
1041

### Key exclusion criteria

Normal subjects:
1. Age: <18 or >90 years old
2. Best corrected visual acuity <= 0.8 (if <50 years old) or <=6/10 (if >50 years old) in study eye
3. Refraction < -10D or >+6D; astigmatism between <- 2D or >2D
4. Abnormal optic nerve head in both eyes ( evidence of excavation, rim thinning, notching, disc hemorrhages, RNFL thinning)
5. IOP > 21 mmHg in both eyes
6. Ocular pathologies, trauma, surgeries (apart from uncomplicated cataract surgery) in both eyes
7. Presence of pathologies that can affect visual field
8. Use of drugs interfering with the correct execution of perimetry
9. Less than two reliable VF exams

Glaucomatous subjects:
1. Age: <18 or >90 years old
2. Best corrected visual acuity <= 0.8 (if <50 years old) or <=6/10 (if >50 years old) in study eye
3. Refraction < -10D or >+6D; astigmatism between <- 2D or >2D
4. Normal optic nerve head in both eyes (according to the specialist opinion at ophthalmoscopy) and normal OCT (ONH and RNFL)
5. Patient not under anti-glaucoma therapy
6. Ocular pathologies, trauma, surgeries (apart from uncomplicated cataract surgery) in both eyes
7. Presence of pathologies that can affect visual field other than glaucoma
8. Use of drugs interfering with the correct execution of perimetry or that would produce visual field loss
9. Less than two reliable VF exams (for example one HFA, one Compass)

### Date of first enrolment
01/09/2015

### Date of final enrolment
30/06/2016

## Locations

### Countries of recruitment
Australia

England

Italy

United Kingdom

United States of America

### Study participating centre
**Ophthalmology Hospital San Paolo in Milan**
Milan

Italy
20142

**Study participating centre**
**Hospital Santa Maria della Misericordia in Udine**
Udine
Italy
33100

**Study participating centre**
**Moorfields Eye Hospital**
London
United Kingdom
EC1V 2PD

**Study participating centre**
**University of Iowa, Carver College of Medicine**
Iowa
United States of America
IA 52242

**Study participating centre**
**University of Melbourne Eyecare**
Department of Optometry & Vision Sciences
Melbourne
Australia
Vic 3010

**Study participating centre**
**IRCCS - Foundation "Bietti GB" for the Study and Research in Ophthalmology ONLUS**
Italy
00198

**Study participating centre**
**Ophthalmology Clinic of the Sant'Andrea Hospital of Rome**
Rome
Italy
00189

# Sponsor information

### Organisation
CenterVue SpA

### Sponsor details
Via San Marco, 9H
Padova
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### Sponsor type
Industry

### Website
http://www.centervue.com

# Funder(s)

### Funder type
Industry

### Funder Name
CenterVue Spa (Italy)

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2019 | 01/09/2020 | Yes | No |

| | | | | |
|---|---|---|---|---|
| Results article | 29/09/2022 | 12/09/2023 | Yes | No |
| Results article | 02/03/2020 | 12/09/2023 | Yes | No |