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Clinical performance of Compass in the diagnosis of glaucoma

Submission date	Recruitment status	[X] Prospectively registered
31/07/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2025	Eye Diseases	

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
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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Observational multicentric cross sectional trial

Study type(s)
Diagnostic

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(s)
Test-retest variability, assessed by parametric statistical methods, on both normal subjects and subjects with glaucoma.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

Australia

Italy

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
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Study participating centre
IRCCS - Foundation "Bietti GB" for the Study and Research in Ophthalmology ONLUS
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Study participating centre
Ophthalmology Clinic of the Sant'Andrea Hospital of Rome
Rome
Italy
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Sponsor information

Organisation
CenterVue SpA

Funder(s)

Funder type
Industry

Funder Name

CenterVue Spa (Italy)

Results and Publications

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
Results article		01/10/2023	01/09/2025	Yes	No