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Visual field testing for glaucoma patients using iPad app

Submission date 23/01/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/02/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/02/2018	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Glaucoma is one of the leading causes of irreversible blindness worldwide. The disease generally does not cause symptoms early as it affects the side-vision or visual field first. Current standard visual field testing machines such as a Humphrey visual field machine are not easily portable and come at a high cost. The Apple iPad however is a popular consumer technology that is portable, relatively low cost and has a high quality screen suitable for vision testing. As part of the treatment of your eye condition you might have had visual field testing on a Humphrey visual field machine, where you are required to keep your eye focused on a point in the center and respond to a white spot shined in your side vision by clicking a button. The aim of this study is to compare visual field testing perform using the Apple iPad against the Humphrey visual field machine over a period of 6 months.

Who can participate?
Adults aged 18 and older who have glaucoma.

What does the study involve?
The participation in the study will last for up to six months for each patient. This is made up of a baseline visit, and visits at one, three, and six months. At each visit participants have their usual visual field test using Humphrey visual field and then visual field test using an iPad. Similar to the traditional Humphrey visual field test, each participant is asked to focus on a red fixation dot and press a button on the keyboard when you see a white spot appear in your side-vision. The software tests each eye separately and takes on average 5 minutes per eye, therefore takes about 10 minutes of testing time.In order to check if the iPad visual field software is able to produce consistent outcomes on multiple occasions across time, participants are also asked to complete the same iPad visual field test again at the one month, three month and six month visits.

What are the possible benefits and risks of participating?
There are no benefits or risks expected with participation.

Where is the study run from?
Addenbrooke's Cambridge University Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2016 to October 2017

Who is funding the study?
Addenbrooke's Charitable Trust, Cambridge University Hospitals (UK)

Who is the main contact?
Dr Yu Xiang George Kong (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Yu Xiang George Kong

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Additional identifiers

EudraCT/CTIS number

IRAS number
204698

ClinicalTrials.gov number

Secondary identifying numbers
IRAS ID: 204698

Study information

Scientific Title
Longitudinal assessment of visual field using iPad tablet computer for patients with glaucoma

Study objectives
Hypothesis is visual field test performed on iPad will be able to produce output measures that matches visual field test performed on the gold standard Humphrey visual field test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority (HRA), 28/09/2016, ref: 204698

Study design
Longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

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

Interventions
The participation in the study lasts for up to six months for each patient. This is made up of a baseline visit, and visits at one, three, and six months.

At each visit participants have their usual visual field test using Humphrey visual field and then visual field test using an iPad. Similar to the traditional Humphrey visual field test, each participant is asked to focus on a red fixation dot and press a button on the keyboard when you see a white spot appear in your side-vision. The software tests each eye separately and takes on average 5 minutes per eye, therefore takes about 10 minutes of testing time.

In order to check if the iPad visual field software is able to produce consistent outcomes on multiple occasions across time, participants are also asked to complete the same iPad visual field test again at the one month, three month and six month visits.

This study does not cause any harm or discomfort to the patient during the test.

Intervention Type
Other

Primary outcome measure
1. Accuracy is measured by comparison of visual field Mean Deviation (MD) and Pattern Deviation (PD) produced by Humphrey Visual field and Melbourne Rapid fields app using

Pearson correlation statistics at all time points (baseline, 1 month, 3 month and 6 month visit)
2. Inter-sesssion reliability is measured using Blandt-Altman analysis comparing the test outcomes at all time points (baseline, 1 month, 3 month and 6 month visit)

Secondary outcome measures
1. Reliability indices on visual field testing is measured using proportions of Fixation loss, False postive and False negative at all time points (baseine, 1 month, 3 month and 6 month visit)
2. Compliance with test-retest regimen is measured using proportion of visits attended at all time points

Overall study start date
01/04/2016

Completion date
30/10/2017

Eligibility

Key inclusion criteria
1. Patients with glaucoma of varying severity (mild, moderate and severe). The eligibility criteria are a diagnosis of glaucoma in one or both eyes (based on characteristic optic disc changes or glaucomatous visual field loss)
2. Visual acuity ≥6/12 vision
3. Aged ≥18 or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients with any significant non-glaucomatous conditions affecting visual function such as cataract, macular degeneration, retinal detachment, diabetic retinopathy, non-glaucomatous optic neuropathy
2. Eye surgery less than 3 months prior to recruitment, because testing of visual field shortly after eye surgery can affect test results.
3. Non-English speaking due to the voice prompt on the software is only available in English.
4. Non-elective hospitalization within the past 60 days that could be of concern in the investigator's judgment.
5. Significant non-visual impairment (eg mobility, verbal communication) preventing the

completion of the objective.
6. Patients who are not able to provide informed consent.

Date of first enrolment
28/09/2016

Date of final enrolment
25/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Cambridge University Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Addenbrooke's Hospital Cambridge University NHS Trust

Sponsor details
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
06/06/2018

Individual participant data (IPD) sharing plan
Clinical information about each patient will also be collected, these include age of patient, treatment history, visual acuity, visual field loss and type of glaucoma (Open angle or close angle or secondary glaucoma). In addition, the visual field testing results obtained from Humphrey Field Analyzer as well as iPad app at all time points (baseline, 1 month, 3 months, and 6 months) will also be stored in the data repository. The results will be de-identified and entered into a database, and will be analysed for significant association.
Consent from participants for data storage is requested as part of the standard informed consent procedure.
Data repository is stored in highly secure local repository provided by Cambridge University HNS Trust. All personnel accessing participant records are required to respect your confidentiality at all times. To ensure privacy, participant's full identity will not appear on any of the study data or samples collected for their analyses. A unique patient number for the study will be used to code any information about the participant. Only principal investigator and authorised personnel will be able to connect this code to the participant, by a list that will be kept securely by the hospital secure data repository for a period of at least 5 years. Study data will be transferred into a computer database and processed to allow the results of this study to be analysed and reported or published. If the results of the study are published, participant identity will remain confidential and de-identified.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.2	06/06/2016	05/02/2018	No	Yes
Protocol file	version V1.2	12/05/2016	05/02/2018	No	No