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Retinal scanning for biomarker discovery in multiple sclerosis

Submission date
18/03/2015

Recruitment status
No longer recruiting

Registration date
20/04/2015

Overall study status
Completed

Last Edited
13/07/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The back of the eye, called the retina, is one of the few places in the human body that allows easy observation of blood vessels and nerves. We are researching how we can use information from images of the retina to help understand multiple sclerosis (MS). Retinal scanning is non-invasive and a completely safe method of obtaining pictures of the retina. Scanning Laser Ophthalmoscopy (SLO) and Optical Coherence Tomography (OCT) use light from low-power lasers which enters the eye through the pupil. Light reflected back leaves the same way to be collected by the machine, creating an image of the retina. Many people have had this type of retinal scanning performed already at visits to an optician for an eye check-up. We now want to analyse these images in more detail to see what they can reveal about diseases such as MS. By applying computational analysis to these images it might be possible to identify subtle changes which may act as early indicators or biomarkers of severity of MS.

Who can participate?
Adults between the ages of 18 and 75 with MS, and healthy volunteers.

What does the study involve?
We will capture retinal images from participants in order to identify candidate retinal biomarkers that could act as early indicators of disease.

What are the possible benefits and risks of participating?
While there is no direct benefit from taking part in our study the results might inform the future healthcare of patients with conditions such as MS. These procedures are completely safe and pose no risk.

Where is the study run from?
The Anne Rowling Regenerative Neurology Clinic (UK)

When is the study starting and how long is it expected to run for?
From April 2015 to April 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Tom MacGillivray

Contact information

Type(s)
Scientific

Contact name
Dr Tom MacGillivray

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRIC/RI/2015/02

Study information

Scientific Title
Multi-modal retinal scanning for diagnostic and therapeutic biomarker discovery in multiple sclerosis and neurodegenerative disease

Study objectives
There is increasing evidence that examining the eye can tell us a lot of information about our health and diseases such heart disease, stroke and dementia. Changes in the eye can sometimes be observed many months or even years before other more serious symptoms develop. We want to study what eyes can reveal about serious diseases like multiple sclerosis (MS), which damage nerves and affects the brain, by analysing images of the retina from simple non-invasive eye scanning. By applying computational analysis to these images it is possible to identify subtle

changes (e.g., variations in retinal vessels, thinning of the retinal nerve fibre layer) which may act as early indicators or markers of severity of MS.

1. Does retinal imaging represent a viable imaging modality for monitoring patients with MS?
2. How does the quality of images acquired from healthy volunteers compare to patients with MS?
3. Does anatomy and function of the retina measured in healthy volunteers differ from patients with MS?
4. Do anatomical and functional changes in the retina show associations or trends with the diagnosis and severity of MS?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - South East, 05/05/2015, ref: 15/LO/0533

Study design
Single-centre trial

Primary study design
Observational

Secondary study design
Cohort 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
Multiple sclerosis

Interventions
We will capture retinal images from consenting patients with MS and also healthy volunteers . We will identify candidate retinal biomarkers that could stratify MS patients, act as early indicators of disease, and be used as outcome measures for studies looking at new therapies.

Intervention Type
Other

Primary outcome measure
The change in retinal structure and function as measured by computation analysis of imaging.

Secondary outcome measures

Visual acuity (full contrast and reduced contrast), refractive error (from glasses or focimeter or refraction), and expanded disability status scale (EDSS).

Correlation will be made with information on diagnosis, subtype, date of onset of symptoms, date of diagnosis, history of optic neuritis, history of other eye diseases, and any current visual symptoms. This will include phenotypic description, disease metric correlation, and integration of retinal image measurements into a combined score.

Overall study start date
01/04/2015

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Competent and consenting adults between the ages of 18 and 75 years
2. Patients with MS including those with clinically isolated syndrome, relapse-remitting, secondary progressive and primary progressive - 25 in each group
3. Participants must be able to manoeuvre themselves to the retinal imaging room in the Rowling Clinic unaided, sit upright in a chair or wheelchair, comfortably position themselves for imaging, and be able to listen to and act upon directions for fixing their gaze

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. People who cannot manoeuvre themselves to the retinal imaging room in the Rowling Clinic unaided, who cannot sit upright in a chair or wheelchair, who cannot comfortably position themselves for imaging, or who would struggle with listening to or acting upon directions for fixing their gaze
2. People under the age 18 or over the age of 75

Date of first enrolment
01/04/2015

Date of final enrolment

01/08/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The Anne Rowling Regenerative Neurology Clinic
49 Little France Crescent
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
The Queen’s Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
University/education

Organisation
NHS Lothian (UK)

Sponsor details
The Queen’s Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
Hospital/treatment centre

Organisation
University of Edinburgh

Sponsor details

Sponsor type
Not defined

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Research organisation

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No