

# Retinal scanning for biomarker discovery in multiple sclerosis

<b>Submission date</b> 18/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/04/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/07/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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**Contact details**  
Centre for Clinical Brain Sciences (CCBS)  
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Edinburgh  
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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Observational

**Study design**

Single-centre trial

**Study type(s)**

Diagnostic

**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(s)**

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

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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**

United Kingdom

Scotland

**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)

## Organisation

NHS Lothian (UK)

## Organisation

University of Edinburgh

## ROR

<https://ror.org/01nrxf90>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No