ISRCTN59449699 https://doi.org/10.1186/ISRCTN59449699

Visualising blood vessel disease in the eye in COVID-19

Submission date
06/08/2020

Recruitment status
No longer recruiting

Registration date
07/08/2020

Overall study status
Completed

Last Edited
29/09/2020

Condition category
Infections and Infestations

[X] 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 coronavirus disease of 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). Since first reported in December 2019, COVID-19 has led to a global pandemic, spreading throughout the world. It is a new disease and the global medical community are still trying to understand how and why the virus makes people sick. Improving this understanding is crucial if effective treatments for this disease are to be developed. Researchers know that, in COVID-19, the blood vessels of many organs become 'sticky', causing clots to form. These clots interfere with the function of the body and can cause serious complications such as pulmonary emboli (PE), stroke and heart attacks. The vessels may also become fragile and leaky causing bleeding.
It is often difficult to do tests specifically to look at the blood vessels in patients who are unwell. However, you can get a direct look at the vessels using a camera to take photographs of the back of the eye. This is known as fundal photography and many people have had this done at their optician or in clinics such as the Diabetic Eye Clinic. We would like to examine how COVID-19 affects the vessels at the back of the eye to help us understand the disease and how it might be more effectively treated.

Who can participate?
Members of the public can enter the study if they are:
• Aged ≥18 years, there is no upper age limit
• Seen in hospital for symptoms related to COVID-19
• Able to understand verbal and written English

What does the study involve?
The researchers will ask participants to do the following:
• Complete a consent form
• Have a bedside photograph taken of the back of each eye
• Permit clinical researchers to record some information about the severity of your illness
The bedside photographs take just a few seconds although there is a flash. Participants will not require dilating eye drops for the photographs. The photograph will remain in their clinical record, but clinical researchers will also analyse them.
If they are well enough, participants will be asked have to a more detailed eye scan known as

optical coherence tomography (OCT). This involves going to a specialised department and is optional. The OCT scan involves looking into a different type of camera and doesn't involve any radiation. It takes a few minutes to perform.
The researchers will also ask if they can access the records of fundal photographs participants have had in the past e.g. at their optician or at the Eye Hospital so that they can compare and analyse these.
They will ask to repeat the photographs (and OCT) in 4 weeks' time with completion of a questionnaire about how participants found the examination. This is optional.

What are the possible benefits and risks of participating?
The photographs of the back of the eye may alert the doctors to problems with the blood vessels that may require treatment. The earlier this is detected, the better. In the longer term, information obtained from this research may lead to routine screening of fundal photographs for those who are unwell with COVID-19 and improvement in the understanding and treatment of COVID-19.
it may be somewhat annoying to have a photograph taken of the eyes when feeling unwell No harm is expected from the photograph. Similarly, there are no particular risks associated with OCT, but it can be wearisome to have an additional test when feeling unwell.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
We will aim to start the study on 16th August 2020 pending regulatory approval. We expect the study to run for 4 months but this will depend on the prevalence of SARS-CoV-2 in the community.

Who is funding the study?
Study funds have been awarded from the Wellcome Trust via the Elizabeth Blackwell Institute Rapid Response Call (COVID-19), University of Bristol and the Department of Neurology Charitable Funds, Southmead Hospital, Bristol.

Who is the main contact?
Dr Claire Rice, C.M.Rice@bristol.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Claire Rice

ORCID ID
https://orcid.org/0000-0002-9851-4426

Contact details
Clinical Neurosciences, Bristol Medical School
University of Bristol
Level 1 Learning and Research Building
Southmead Hospital

Bristol
United Kingdom
BS10 5NB
+44 (0)1174146695
c.m.rice@bristol.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
286315

Study information

Scientific Title
Visualising vasculopathy in COVID-19 using portable fundoscopy

Acronym
VisVasc COVID-19

Study objectives
Bedside, hand-held fundoscopy can be used to assess quantitatively the effects of COVID-19 on retinal vasculature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2020, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8010, +44 (0) 207 104 8221, +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), REC ref: 20/NW/0363

Primary study design
Observational

Study design
Single-site observational feasibility study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
1. Perform bedside fundal photography with or without optical coherence tomography on patients with COVID-19 at baseline and 4 week follow up
2. Assess tolerability of bedside fundal photography by recording adverse events and using patient and clinician self-report intervention acceptability questionnaires
3. Quantify retinal vascular abnormalities and compare them with historical patient records and/or age-matched controls

4. Analyse data to inform outcome measures to determine whether retinal vasculopathy predicts COVID-19 severity risk

Intervention Type
Other

Primary outcome(s)
1. Safety of performing the study measured using adverse events reported throughout the study
2. Tolerability of the study measured using a modified version of participant and clinician self-report intervention acceptability questionnaire at a single time

Key secondary outcome(s)
1. Retinal vascular abnormalities will be quantified using proxy-Early Treatment Diabetic Retinopathy Study (ETDRS)/International Clinical Grading system grading of retinopathy and maculopathy and artificial intelligence software (e.g. EyeArt™) using fundal photography at baseline and 4 weeks
2. Macular and peripapillary retinal thickness and the thickness of the retinal layers will be analysed according to standard retinopathy parameters using optical coherence tomography data at baseline and 4 weeks (where available)

Completion date
05/08/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/09/2020:
1. Emergency Department or hospital admission for symptoms related to COVID-19
2. Aged ≥18 years or over, there is no upper age limit

Previous inclusion criteria:
1. Emergency Department or hospital admission for symptoms related to COVID-19
2. Aged ≥18 years
3. Fluency in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. COVID-19 patients receiving palliative care
2. Eye disease precluding fundoscopy
3. Significant agitation precluding safe practice of fundoscopy

Date of first enrolment
28/09/2020

Date of final enrolment
28/01/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Department of Neurology
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust via Elizabeth Blackwell Institute, University of Bristol

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Southmead Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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