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Optical electromyography for the diagnosis of nerve and muscle disorders

Submission date
27/02/2026

Recruitment status
Not yet recruiting

Registration date
13/04/2026

Overall study status
Ongoing

Last Edited
13/04/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
This study is testing a new technique to see whether the protocol can improve the care of patients under investigation for diagnosing nerve and muscle disorders. A commonly used test for this is 'EMG', which stands for electromyography. This involves placing a very thin needle into the muscle and recording electrical activity. It has been used for over 50 years, so it is a very well-established test.

The current study will test a new type of EMG needle called Optical EMG. It contains additional channels to shine light into the muscle. This light might provide useful information and help diagnose conditions more quickly. The 'optical' part is about using light to study muscle health. This is done by shining light of a particular wavelength, or colour, into the muscle. The light interacts with the muscle and, as a result, it changes. These changes may be different in healthy muscle versus different nerve/muscle diseases. This technique is called Raman spectroscopy. It is currently being investigated as a way to diagnose lots of different conditions.

Who can participate?
Adult healthy volunteers, patients with inclusion body myositis (IBM), and patients undergoing investigation for motor system disorders.

What does the study involve?
Routine EMG, followed by EMG and Raman spectroscopy of their muscles (up to 2 muscles with each technique).

What are the possible benefits and risks of participating?
There is no direct benefit to participating in the study. However, it will contribute to the development of a new diagnostic technique. If successful, this will give patients access to instant diagnosis of conditions that can currently take months to diagnose and involve invasive procedures like biopsies.

Where is the study run from?
The University of Exeter, UK, sponsors the research, and the project is run from the University of Sheffield, UK.

When is the study starting and how long is it expected to run for?
December 2026 to December 2027.

Who is funding the study?
1. MRC, Developmental Pathway Funding Scheme (DPFS), UK.
2. National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
1. Dr James Alix, University of Sheffield, j.alix@sheffield.ac.uk
2. Dr Alex Dudgeon (Admin contact), a.dudgeon@exeter.ac.uk

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Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
322129

Central Portfolio Management System (CPMS)
71707

Study information

Scientific Title
Optical EMG for the diagnosis of nerve and muscle disorders

Acronym
Optical-EMG

Study objectives
Can the optical EMG probe be used safely on muscle tissues in vivo to measure tissue spectra and collect EMG recordings?

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Observational

Study design
Feasibility/pilot first-in-human clinical study, involving a case series of healthy volunteers and two patient groups

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nerve and muscle disorders

Interventions
We plan to study healthy volunteers and two patient groups. We will discuss each in turn.

Healthy volunteers
We will recruit healthy volunteers via local advertisement of the study. Following consent, participants will have a standard EMG performed by an experienced consultant in their dominant arm and leg. So, if they are right-handed, this would be their right arm and right leg. The EMG test will be performed on a muscle in the shoulder and a muscle in the thigh. For this, the needle will be inserted into the muscle, and the patient will be asked to move the muscle. The electrical activity will then be recorded. They will then be asked to relax the muscle, and the electrical activity will stop. This will be done in one or two places in the muscle, as per standard EMG practice.

After standard EMG, optical EMG will be performed on the opposite side. Before this starts, the participant will put on some special goggles. This is because the laser light could affect the eyes if shone directly into the eye. This will not happen, as the light will only be turned on when the

needle is inside the muscle, but it is a standard precaution to take. First, the electrical part of the recording will proceed in the same way as above. Then, with the muscle relaxed, the light will be turned on for around one minute. The needle will then be moved to another part of the muscle and another reading taken. This will be done in the shoulder and thigh muscles. This will usually mean a total of 4 measurements taken. We will allow for a 5th if a problem arises during one of the recordings, for example, if the patient moves. After both standard EMG and optical EMG have been performed, the participant will be given a questionnaire about how painful each test was.
The first 5 participants will then undergo an MRI scan of the muscles on both sides. This is so we can compare any changes in the muscles for both standard EMG and optical EMG. Another MRI will take place 2 days later. If there are signs of muscle inflammation, another scan will be repeated two weeks later. Participants after the first 5 will just undergo EMG and optical EMG, with no MRI. Other than a mild ache immediately after the procedure, which is common for standard EMG, we do not anticipate any significant symptoms such as long-lasting pain or weakness. If this happens, the participant will be instructed to contact their GP and the study team, and further care will be initiated as appropriate.

Patients under investigation for MND
These patients will be under investigation for their symptoms and will have been referred for standard EMG at the Royal Hallamshire Hospital. For appointments, we send out a ring-in letter to the patients, who then call the department to make their appointment. Alongside the ring in the letter, we will include study information. When the patient calls, the member of staff making the call will ask if they would like to participate in the research. If so, they will be booked into a dedicated research clinic. On the day of this appointment, the clinician performing both the research and the routine appointment will discuss the study and answer any questions. If the patient wishes to participate, then written consent will be taken. The routine EMG test will then be performed as per standard clinical practice. Once the standard test is completed, the optical EMG test will be performed, followed by the pain questionnaire.

Patients with inclusion body myositis
Sheffield Teaching Hospitals keeps a database of patients with nerve and muscle conditions for the purpose of improving clinical care through research. Patients diagnosed with this condition will be sent a letter of invitation and the study information. They will be asked to contact the department if they would like to be contacted. They may also be called to see if they would like to participate. If so, the patients will come to the department, any questions answered, and informed consent taken. The measurements will then be performed: first, standard EMG and then optical EMG. The same muscles as for the other participant groups will be measured. The side will depend upon the patient's symptoms; for example, it would be standard practice to do the EMG on the most affected side. The pain questionnaire will then be completed.

Finally, the two patient groups will also be invited to a focus group towards the end of the study. This could be face-to-face or online, depending upon preference. There will be two meetings. The purpose of the first is to collect group feedback on the optical EMG test and on our plans for the next study. The second will focus on how patients were diagnosed, what they thought went well, and what could be improved in the diagnostic pathway. This will help us understand where optical EMG could be placed to maximise benefit.

Intervention Type
Other

Primary outcome(s)

1. Safety of the Optical EMG probe measured using the occurrence of device-related adverse events and MRI evidence of tissue injury in the first five healthy volunteers at an immediate time point after the procedure and again at 2 days and up to 2 weeks if inflammation is detected

Key secondary outcome(s)
1. Feasibility of obtaining Raman spectra from muscle tissue measured using successful acquisition of analyzable spectra during the optical EMG procedure at a single study visit

2. Diagnostic performance of Raman spectra measured using multivariate analysis, comparing optical EMG data across healthy, MND, and IBM groups at a single study visit

3. Usability of the Optical EMG probe measured using operator assessment of ergonomics and ease of use, recorded at the time of the procedure

4. Participant pain and tolerability measured using a pain questionnaire at an immediate time point after both routine EMG and optical EMG during the single study visit

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Healthy volunteers
1.1. Male or female participants, aged 18-90 years
1.2. No known neurological diagnoses
1.3. No symptoms suggestive of weakness in the arms or legs
2. Patients under investigation for suspected motor neurone disease
2.1. Male or female participants, aged 18-90 years
2.2. Undergoing neurophysiological assessment for their symptoms, where one of the differential diagnoses includes motor neurone disease or its subtypes, e.g. amyotrophic lateral sclerosis, primary muscular atrophy, primary lateral sclerosis.
3. Patients with a diagnosis of inclusion body myositis
3.1. Male or female participants, aged 18-90 years
3.2. Diagnosis of inclusion body myositis meeting the 2024 ENMC Criteria

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
All participants:
1. Known bleeding/clotting disorder
2. Taking anti-coagulation medications, e.g. warfarin, direct oral anticoagulants.
3. Pregnancy
4. Lacks capacity to provide informed consent

Healthy volunteers only:
1. Contraindication to MRI (as healthy volunteers may undergo an MRI scan of their muscles)

Date of first enrolment
01/12/2026

Date of final enrolment
01/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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England
S5 7AU

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication