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A study to identify if it is possible to measure lactate in health participants and people with myalgic encephalomyelitis during everyday activity

Submission date
12/04/2024

Recruitment status
No longer recruiting

Registration date
15/04/2024

Overall study status
Completed

Last Edited
27/12/2024

Condition category
Nervous System Diseases

[ ] 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
Myalgic encephalomyelitis (ME) is a "complex, acquired multi-systemic disease with a profound dysfunction/dysregulation of the neurological control system resulting in faulty communication and interaction between the nervous system and major body systems". Up to 80% of cases of ME are post-viral. Symptoms include fatigue, post-exertional malaise (PEM), difficulties with thinking and memory (cognitive), pain and many more symptoms. The defining feature of ME is PEM after physical, cognitive, emotional and social activity. There are over 30 symptoms of PEM including brain fog, muscle pain, fatigue, flu-like symptoms and difficulty sleeping. There is a delay between a triggering activity and the onset of PEM usually 2-7 days after but this may vary. Symptoms usually last days to weeks, but again can vary. It is unclear what causes PEM. One area of research using cardiopulmonary exercise testing (CPET), exercising to the maximum on a bike or treadmill, has shown that people with ME switch from aerobic to anaerobic metabolism too soon leading to an increased production of lactate as a by-product of anaerobic metabolism. People with ME have raised lactic acid during these CPET tests and this happens sooner than healthy comparators. However, people with ME say that they feel that they have a buildup of lactate during everyday activity. No research has explored this in healthy people or in people with ME. The aim is to conduct a pilot study to identify the feasibility of measuring the lactate levels of people with ME and healthy volunteers.

Who can participate?
People with ME, using the ICC diagnostic criteria (excluding the very severe), and 20 healthy volunteers (matched with the people with ME by age and sex)

What does the study involve?
The study involves doing a 10-minute stand test, collecting lactate levels over 3 days (7 on day 1, 4 on day 2 and 7 on day 3), and filling out three questionnaires and activity and symptom diaries over the 3 days of testing. People with ME will be tested in their own homes and healthy participants either in their own homes or at the University of Liverpool.

What are the possible benefits and risks of participating?
Repeated use of a lactic acid monitor over 2 non-consecutive days can cause discomfort in the fingertips used to test. Carrying out the 10-minute stand test for people with orthostatic intolerance (OI) can cause dizziness and there is a risk of falls. Therefore, this test will be carried out by a qualified physiotherapist who has conducted this test with many people with OI and has been qualified for over 30 years. If the participant demonstrates any abnormalities with this test she will stop the test and monitor the participant until normal values are achieved. Any abnormalities will be recorded and reported to their GP. For people with ME, taking part will identify if they have abnormal levels of lactic acid compared to a healthy person their age and gender. For everyone, this is important information that could be used to help understand the physiological differences between people with ME and those without. Participants will be helping people with ME in the future to determine differences they may have and can help clinicians learn if there is a way to help people with ME. Both groups will be entered into a draw to receive £50.

Where is the study run from?
The University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
January 2024 to December 2024

Who is funding the study?
The ME Association (UK)

Who is the main contact?
Dr Nicola Clague-Baker, nicola.baker@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
13358

Study information

Scientific Title
A pilot study to identify if it is feasible to measure lactate in health participants and people with myalgic encephalomyelitis during everyday activity

Study objectives
No hypothesis as it is a feasibility study

The aim is to carry out a pilot study to determine the feasibility of measuring lactate levels of healthy and myalgic encephalomyelitis (ME) participants during everyday activity.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/01/2024, Central University Research Ethics Committee, University of Liverpool (Brownlow Hill, Liverpool, L69 3GB, United Kingdom; +44 (0)151 794 8290; ethics@liverpool.ac.uk), ref: 13358

Study design
Pilot feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet

Not available in web format, please use contact details to request a participant infomration sheet

Health condition(s) or problem(s) studied
Myalgic encephalomyelitis

Interventions
Adverts are placed on the ME Association and PhysiosforME website as well as their Facebook pages and Twitter pages with a copy of the participant information sheet. If the participant is interested they are directed to contact the PI Dr Nicola Clague-Baker by email. She will then follow up with an email to arrange a follow-up telephone call or Zoom call. The participant will then speak to Dr Clague-Baker to explain the study and ask any questions and then see if they fit into the inclusion criteria for the study. If they are suitable a date for the first appointment is arranged.

On the day of the assessment (arranged to fit into the participant's schedule – at home if they are a person with ME and at the university if they are a staff member or a student at the university), they will be asked to fill out the consent form and two questionnaires (which can be completed in their own time if it is too much on the day of the assessment). Their medical history and medications will also be recorded but they can send that through separately if it is too much to do it all in one session. They will then lie for 5 minutes and stand for up to 10 minutes and their blood pressure (BP), heart rate (HR) and oxygen levels with a pulse oximeter will be taken before and after each activity.

They will then be asked to record their lactic acid levels seven times on an active day, four times on the second day and seven times on the third day using a lactic acid monitor. Seven times: 1. on waking, 2. 1 hour after breakfast, 3. Before lunch, 4. 1 hour after lunch, 5. Before dinner, 6. 1 hour after dinner, 7. Before going to bed. Four times: 1. on waking, 2. 1 hour after breakfast, 3. 1 hour after lunch, 4. Before going to bed. They will also be asked to record their activity (type and time) and food and drink (type and time). The research assistant will provide the lactic acid monitors for the participants without ME. She will teach them how to use the device and will also provide printed information about the procedure. The PI will provide the lactic acid monitors for the participants with ME. She will teach them how to use the device and will also provide printed information about the procedure. In addition, the researchers will ask them to wear an elasticated belt with an accelerometer or pedometer over the 3 days so that they can record their activity levels. The PI will also be available via phone and email if they have any problems with the devices or the use of the devices. After the 3 days the PI will return to pick up the questionnaires, diary and equipment (if an ME participant) and the research assistant will do the same for the healthy participants.

Intervention Type
Other

Primary outcome measure
Lactate measured using a Lactate Pro-2 monitor over 3 days, day 1, day 2 and day 3

Secondary outcome measures
1. Fatigue and ME symptoms measured with the Depaul Symptom Questionnaire - short form - once on assessment
2. Physical function measured with the PROMIS Short form - fatigue - once on assessment
3. Fatigue measured with the PROMIS Short form - physical function - once on assessment

Overall study start date
06/01/2024

Completion date
30/12/2024

Eligibility

Key inclusion criteria
The International Consensus Criteria (ICC) will be used for people with ME. People with different severities of ME will be recruited ranging from mild to severe ME.

20 people without ME will be matched to the ME participants based on age and gender. They will be recruited from the University of Liverpool student and staff population and family members and friends of the ME participants.

Additional inclusion criteria:
1. No history of medical conditions
2. Able to give informed consent

Participant type(s)
Healthy volunteer, Service user

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Total final enrolment
38

Key exclusion criteria
1. People with very severe ME
2. Unable to take self-measurements with the portable lactic acid monitor

Date of first enrolment
06/02/2024

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
All recruitment is online
United Kingdom
-

Sponsor information

Organisation
University of Liverpool

Sponsor details
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United Kingdom
L69 3GB
+44 (0)151 795 7357
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Sponsor type
University/education

Website
https://www.liverpool.ac.uk/intranet/health-and-life-sciences/clinical/clinical-research-governance/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
ME Association

Alternative Name(s)
Myalgic Encephalopathy Association, Myalgic Encephalomyelitis Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Plan to publish January 2025
Results will also be disseminated at the Chartered Society of Physiotherapy conference

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
Individual participant information will be provided for each participant.
The name and email address of the investigator/body who should be contacted for access to the datasets: Dr Nicola Clague-Baker (nicola.baker@liverpool.ac.uk)
The type of data that will be shared: Anonymised results of all the outcome measures.
Dates of availability: December 2024.
Whether consent from participants was required and obtained: Yes, required and obtained.
Comments on data anonymization: Data is anonymised on the first assessment.

IPD sharing plan summary
Available on request