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Sudden cardiac death risk evaluation using personalised electrophysiological, autonomic and mental health assessment following myocardial infarction

Submission date 20/04/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/04/2026	**Overall study status** Ongoing	
Last Edited 20/04/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

After a person has a heart attack, their heart is damaged. For most people, their hearts keep working fine. But for a small group, this damage can cause an electrical "short circuit." This makes the heart stop beating suddenly, which causes death. Doctors have a device called an ICD that can be put inside a person’s chest during surgery. If the heart short-circuits, this ICD device shocks it back to life. Currently, it is unknown how to precisely measure the danger of a short circuit to decide who needs an ICD device. The tests used to decide who needs an ICD device are not accurate enough. This means that many people get surgery who don't need it, and others who need it are missed. This happens because of missing Information, where researchers have not been looking at all the right signs, and one size doesn’t fit all, instead of using general rules. The project goal is to create a better test to predict who is in danger, and to understand if a patient's sadness or anxiety might keep their heart stable.

By looking at the heart and the brain, this study hopes to:
• Develop an accurate and affordable test to tell healthcare professionals who need a life-saving ICD device.
• See if helping people feel happier and less worried can actually protect their hearts
• Set up future studies looking at new treatments which keep the heart stable.

Who can participate?

Patients aged over 18 who are post-MI, with STEMI within 40 days to 3 months, and healthy volunteers aged 18 and over.

What does the study involve?

Measuring individual risk

A new computer test has been created called LifeMap. It can directly measure the risk of a short circuit in the heart for each person. There are also tools to check the electrical signals in the nerves. It is thought that "stress messages" from the brain travel down these nerve wires. These

messages might make the heart unstable, increasing the chance of a dangerous short circuit - something that LifeMap allows us to measure.

Check the Short Circuit Risk:
• The study will compare heart signals after a heart attack with healthy hearts using the LifeMap computer test to measure the electrical stability of patients' following a heart attack whilst measuring the impacts of signals from the brain and nerves.
• To understand feelings and mental health, patients will be asked about their mental health to see if feeling sad or worried makes their heart and nerves more unstable and prove that this can be measured.

What are the possible benefits and risks of participating?
Participation will aid in improving medical risk tools, including the LifeMap technology, potentially leading to better prediction and prevention of sudden cardiac death (SCD) for future patients. Aiming to reduce unnecessary ICD insertion and find those who would benefit from an ICD and currently would not be offered one. Much of the work planned is under-researched and the results of the study aim to provide new information to the scientific community, including links between mental health and recovery after a heart attack.

As with any medical procedure, there are some risks and possible side effects. Exercise tests are generally a very safe procedure and serious complications are rare, but can include fast or slow heart rhythms, fainting and falls in blood pressure. Participants will be asked to pause heart rate-altering medicines for the exercise tests. Stopping these medications for a short period is usually well tolerated; however, some withdrawal side effects can occur, such as headache, tiredness and a rise in blood pressure.

Where is the study run from?
University of Leicester, UK.

When is the study starting and how long is it expected to run for?
April 2026 to September 2029.

Who is funding the study?
The Kusuma Trust, UK.

Who is the main contact?
Dr Edward Lau, el203@leicester.ac.uk

Contact information

Type(s)
Scientific, Public, Principal investigator

Contact name
Dr Edward Lau

ORCID ID
https://orcid.org/0000-0002-9640-3343

Contact details

University of Leicester
Leicester
United Kingdom
LE1 7RH
+44 0116 373 6508
el203@leicester.ac.uk

Type(s)
Principal investigator, Scientific

Contact name
Prof G André Ng

ORCID ID
https://orcid.org/0000-0001-5965-0671

Contact details
University of Leicester
Leicester
United Kingdom
LE1 7RH
+44 0116 373 6508
andre.ng@leicester.ac.uk

Type(s)
Scientific

Contact name
Dr Will Nicolson

ORCID ID
https://orcid.org/0000-0002-5718-8767

Contact details
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP
+44 0300 303 157
will.nicolson@nhs.net

Type(s)
Scientific

Contact name
Dr Xin Li

ORCID ID
https://orcid.org/0000-0002-4018-6220

Contact details

University of Leicester
Leicester
United Kingdom
LE1 7RH
+44 0116 373 6508
xin.li@leicester.ac.uk

Type(s)
Scientific

Contact name
Dr Sarah Gunn

ORCID ID
https://orcid.org/0000-0002-8492-060X

Contact details
University of Leicester
Leicester
United Kingdom
LE1 7RH
+44 0116 373 6508
sarah.gunn@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
355700

Protocol number
1083

Study information

Scientific Title
SUdden death Risk eValuatIon and VulnErability post-Myocardial Infarction

Acronym
SURVIVE-MI

Study objectives
The primary objective is investigating the performance of LifeMap sudden cardiac death risk using non-invasive measures

Key research questions:
• Can autonomic and cardiac restitution differences be measured between infarcted versus healthy myocardium
• Understanding the effect of different exercise modalities and regimens on cardiac electrophysiological measures including non-invasive LifeMap measures
• What is the impact of mental health on autonomic and cardiac restitution and is this different

between infarcted versus healthy myocardium
• To what extent does post-MI cardiac dysfunction impact anxiety and depression
• Does comorbid anxiety or depression in post-MI patients represent a distinct "higher-risk phenotype" that warrants consideration in risk tools
• Can we measure how changes in the autonomic nervous system including severity of anxiety and depression link to cardiac electrical instability and sudden cardiac death risk.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/02/2026, London South East REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8000; londonsoutheast.rec@hra.nhs.uk), ref: 26/LO/0063

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Sudden cardiac death following myocardial infarction

Interventions
Suitable patients following MI will be approached alongside controls without cardiac disease to participate in the prospective cohort study.

All participants will attend a treadmill exercise study and be given a 24-hour ECG monitor; subgroups will be determined based on left ventricular ejection fraction. Electrogram and exercise data will be compared between post-MI participants and controls.

Validated questionnaires will measure baseline symptoms and demographics, including anxiety and depression burden, quality of life, health literacy and autonomic symptom burden.

Subgroups of the post-MI participants will be invited to focus groups to understand the lived experience following acute MI.

Control arm participants will complete the stationary bike exercise test to compare electrophysiological, exercise and LifeMap outcomes between exercise modalities and regimens.

Intervention Type
Other

Primary outcome(s)
1. Assess if Non-Invasive LifeMap metric (R2I2) is elevated in patients following MI compared to healthy controls and the impact of LVEF measured using Exercise Electrocardiogram at 40 days - 3 Months Following MI

Key secondary outcome(s))

1. Predictive capacity of cardiac autonomic dysfunction and NI-LifeMap measured using SCD Mortality event at 12 Months

2. Explore the measurability of autonomic differences by severity of anxiety and depression and association with cardiac electrical instability measured using Electrocardiogram at 40 days - 3 Months Following MI

3. Determine the Relative Autonomic symptom burden, Anxiety symptom burden, Depressive symptom burden, quality of Life, and health literacy levels in the post-MI cohort measured using questionnaire data at 40 days - 3 Months Following MI

4. Explore the association of mental health with adverse cardiovascular outcomes measured using composite endpoint of SCD, non-arrhythmic cardiovascular event, non-fatal MI and hospitalisation at 12 months

5. Understand the lived experiences of individuals with anxiety following acute MI measured using focus groups at less than 12 months post MI

6. Assess the impact of mental health symptom burden on healthcare interaction and compliance measured using symptom burden seen on questionnaire data with community prescription dispensing and secondary care records at 12 months

7. Assess the reproducibility and quality of non-invasive LifeMap measures and QT dynamics measured using treadmill and bike exercise at 40 days - 3 Months Following MI

8. Assess QT dynamics of post MI patients compared to healthy controls measured using Electrocardiogram at 40 days - 3 Months Following MI

9. Assess the effect of rate of change of HR change on the QT relationship measured using Electrocardiogram at 40 days - 3 Months Following MI

10. Assess the heart rate recovery relationship with cardiac events and measures of autonomic dysfunction measured using Exercise Electrocardiogram at 40 days - 3 Months Following MI

11. Assess the risk stratification of non-invasive LifeMap to predict outcomes compared to current guidelines measured using SCD events at 12 Months

12. Assess SCD events in relation to cardiac autonomic dysfunction and non-invasive LifeMap measured using Electrocardiogram and study measurements at 12 Months

Completion date
02/09/2029

Eligibility

Key inclusion criteria
Post-MI Inclusion Criteria
1. Patients aged over 18
2. STEMI within 40 days to 3 months

Control Inclusion Criteria
1. Over the age of 18
2. Able to consent to the study independently
3. Considered to be fit enough to be able to complete the full repeat measure exercise protocol

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Post-MI Exclusion Criteria
1. Diagnosis of a non-ischemic cardiomyopathy
2. Inherited cardiac conditions which have an increased risk of SCD, including inherited structural diseases and channelopathies
3. Presence of severe comorbid conditions limiting life expectancy to less than 1 year
4. Contraindications to exercise study
5. Inability to consent to the study
6. Atrial fibrillation
7. Planned or outstanding coronary percutaneous or surgical revascularisation
8. Deemed unable to participate in an exercise study targeting achievement of maximal heart rate , based on existing functional or symptomatic limitations
9. Inability to understand written and verbal English to enable safe participation on dynamic exercise testing

Control Exclusion Criteria
1. Previous cardiac diagnosis including acute coronary syndrome/cardiac surgery, angina, severe valvular heart disease, arrhythmia
2. Previous cardiac intervention including Implanted pacemaker, cardiac surgery
3. Deemed unable to participate in an exercise study targeting achievement of maximal heart rate , based on existing functional or symptomatic limitations
4. Contraindications to exercise study
5. Inability to understand written and verbal English to enable safe participation on dynamic exercise testing

Date of first enrolment
30/04/2026

Date of final enrolment
02/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester
Glenfield Hospital
Groby Road
Leicester
England
LE3 9QP

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type

Funder Name
The Kusuma Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available