ISRCTN23174569 https://doi.org/10.1186/ISRCTN23174569

Can changes in myocardial work and right ventricle free wall strain predict 30-day mortality in critical care patients presenting with sepsis?

Submission date
24/03/2021

Recruitment status
No longer recruiting

Registration date
12/04/2021

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sepsis is a leading cause of death and disability in critical care units worldwide. Sepsis affects all the major organ systems within the body but it is still not fully understood how sepsis affects organs, and in particular, the heart. In sepsis, there can be varying stress placed on the heart and it may take up to 10 days to fully recover once the patient has been successfully treated. However, it is still not fully understood the initial effects that sepsis has on the heart and the stress placed on the heart may not be appropriately recognised with the current standard measures of heart function.

This study aims to measure the effects of sepsis on how much energy and stress the heart uses and generates to pump blood, using echocardiography (the same non-invasive technology that is used in pregnancy to image a mother's baby). From these images, the study team will be able to calculate the amount of work done and strain the heart is placed under using specialized computer software. This non-invasive echocardiography is now a standard of care for patients being admitted to critical care. Using this software the study team will extract as much information as possible from the images, to hopefully help to identify patients early that may benefit from changes to their sepsis management. These analyses could be useful as they can be completed from a standard echocardiogram of the chest with no extra views or tests needed. This study also aims to compare the energy spent (or work done) by the heart in sepsis against standard measures of heart function.

Who can participate?
Adult patients admitted to critical care with a severe infection needing more organ support that can be given on normal wards.

What does the study involve?
The study involves identifying very sick patients that present to critical care with infection (sepsis) and using ultrasound to image their heart within 24 h of admission, then between 48 and 72 h after admission.

What are the possible benefits and risks of participating?
Increased surveillance of heart function on day 3 is of potential benefit as it will give greater insight into how well the heart is functioning using ultrasound. There is a very small risk of bruising associated with the placement of the probe against the chest wall, but this is transient and will resolve within hours.

Where is the study run from?
Critical Care Unit at Surrey and Sussex Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
From January 2019 to December 2023

Who is funding the study?
The Critical Care Department at Surrey and Sussex Healthcare NHS Trust (UK)

Who is the main contact?
Dr Theophilus Samuels, theophilus.samuels1@nhs.net

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262520

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 262520

Study information

Scientific Title
myoCardial work and Right ventricle Strain In Sepsis (CRiSIS): new investigations in critical care echocardiography

Acronym
CRiSIS

Study objectives
Current study hypothesis as of 18/10/2024:
As no specific data are available on the assessment of myocardial work (MW) and minimal data on right ventricle free wall strain (RV FWS) in patients presenting with sepsis to critical care, this study aimed to:
1. Investigate if MW and RV FWS measured on days 1 and 3 of admission are associated with 30-day mortality
2. Investigate if any association exists between the interval changes (i.e. the difference in measurements recorded on day 1 and day 3 of their admission) in MW and RV FWS on 30-day mortality
3. Assess if any differences exist on day 1 between male and female patients in MW and RV FWS
4. Provide insights into the degree to which myocardial work and RV FWS are associated with Global Longitudinal Strain (GLS) and left ventricular ejection fraction (LVEF)

Previous study hypothesis:
1. Measuring how much work the heart uses to interrogate cardiac function and determine if changes over a 72 h period can help to predict mortality at 30 days
2. Right ventricle free wall strain (RVFWS), the strain that the right ventricle is placed under when it beats), will also add further evidence to our currently limited knowledge on the association between sepsis and RVFWS
3. Comparing the left ventricle strain and right-side free wall strain against each other may demonstrate an interactive effect due to the phenomenon of ventricular interdependence
4. To create a model to predict the outcomes in patients presenting with sepsis for validation in future studies, in the hope that it can be used to improve outcomes and treatment strategies

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/05/2021, London Bromley Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; approvals@hra.nhs.uk), ref: 21/LO/0303

Study design
Single-centre prospective observational cohort pilot study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Critical care patients admitted with sepsis

Interventions
Current interventions as of 21/10/2024:
Participant hearts will be examined using standard transthoracic echocardiogram (TTE) on 1 and 3 days of admission to ICU. From these images, the study team will be able to calculate the amount of work done by the heart muscle and strain the heart is placed under using specialized computer software. Non-invasive echocardiography is now a standard of care for patients being admitted to critical care. By using this software, the study team will extract as much information as possible from the echocardiography, which will hopefully help to identify patients early that may benefit from changes to their sepsis management.

The study team also wishes to compare the energy spent (or work done) by the heart in sepsis against standard parameters of heart function. It has recently been shown that these correlate well in healthy patients, and therefore, it is important to assess if this correlation persists in sepsis.

Lastly, what is favourable about these analyses is that they can be completed from a standard transthoracic echocardiogram (TTE) with no extra views or tests needed. They are in effect, tasks that can be done on a computer. In addition, this measurement is less load-dependent than other standard measures used (it does not depend that much on external factors that can reduce the ability of the heart to pump blood, such as a very high blood pressure).

Previous interventions:
Participant hearts will be examined using standard transthoracic echocardiogram (TTE) on 1, 3, and 90 days of admission to ICU. From these images, the study team will be able to calculate the amount of work done by the heart muscle and strain the heart is placed under using specialized computer software. Non-invasive echocardiography is now a standard of care for patients being admitted to critical care. By using this software, the study team will extract as much information as possible from the echocardiography, which will hopefully help to identify patients early that may benefit from changes to their sepsis management.

The study team also wishes to compare the energy spent (or work done) by the heart in sepsis against standard parameters of heart function. It has recently been shown that these correlate

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Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 21/10/2024:
Prediction of mortality at 30 days using myocardial work (MW) and right ventricle free wall strain (RVFWS) measured using transthoracic echocardiography on 1 and 3 days of ICU admission

Previous primary outcome measures:
1. Prediction of mortality at 30 days using myocardial work (MW), Global Longitudinal Strain (GLS), and right ventricle free wall strain (RVFWS) measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission
2. Determining the clinically relevant level of correlation between mortality at 30 days and changes in MW, Global longitudinal strain (GLS) and RVFWS measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission and participant records between baseline and hospital discharge

Secondary outcome measures
Previous secondary outcome measures as of 21/10/2024:
1. Association between MW, RVFWS with global longitudinal strain (GLS) and left ventricle ejection fraction (LVEF) measured using a non-parametric bootstrapping method on day 1 and day 3
2. Assess if any differences exist between male and female patients in MRW and RVFWS measured using permutation tests on admission (day 1)

Previous secondary outcome measure:
1. Association between changes in MW, GLS, and RVFWS and length of stay in ICU measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission and participant records between baseline and hospital discharge
2. Association between changes in MW, GLS, and RVFWS to days on mechanical ventilation (if part of patient's clinical management) measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission and participant records between baseline and hospital discharge
3. Prediction of mortality at 90 days predicted from measurements of MW, Global Longitudinal Strain (GLS), and right ventricle free wall strain (RVFWS) measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission
4. Changes in MW, RVFWS, and GLS measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission
5. Feasibility of obtaining suitable images measured using transthoracic echocardiogram at 1, 3, and 90 days of ICU admission

Overall study start date
01/01/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Admission diagnosis of sepsis
3. Standard of care echocardiogram within 24 h of admission to ICU
4. Adequate echocardiography image quality that permits cardiac work analysis and/or strain assessment of the right ventricle free wall
5. Able to speak, understand and communicate in English
6. Written or verbal informed consent from the patient or next of kin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
39

Key exclusion criteria
1. Atrial fibrillation
2. Previous cardiac surgery
3. Pregnancy
4. Severe valvular disease
5. Inadequate echocardiography image quality

Date of first enrolment
01/05/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Surrey Hospital
Surrey and Sussex Healthcare NHS Trust
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.surreyandsussex.nhs.uk/

ROR
https://ror.org/0480vrj36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Critical Care Department, Surrey and Sussex Healthcare NHS Trust

Results and Publications

Publication and dissemination plan
The results of this study will be submitted for publication in peer-reviewed journals and presented at relevant conferences. The patient information sheet will inform participants that the results will be published in a scientific journal.

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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
Results article		13/05/2025	16/07/2025	Yes	No