

Assessing acute and late developing heart function in patients with sepsis and septic shock with cardiac ultrasound

Submission date 19/11/2020	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 07/12/2020	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/05/2023	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to investigate if new ultrasound techniques together with blood samples may help to detect heart failure sooner than current methods in patients who are in the Intensive Care Unit with sepsis or septic shock. The study will also involve follow up with further ultrasound scans and blood tests after patients have recovered to see if more information can be found on what happens to heart function after leaving the hospital. This has not been investigated before.

Who can participate?

Any adults meeting the inclusion criteria of sepsis or septic shock while a patient within the participating centre critical care unit, and without meeting any exclusion criteria.

What does the study involve?

The study involves blood tests and ultrasound scans of the heart at 4 different times over 90 days and a phone call to participants 1 year after starting the study.

What are the possible benefits and risks of participating?

There are no benefits to participation aside from having regular heart scans which may pick up incidental findings

Where is the study run from?

Queen Alexandra Hospital, Portsmouth Hospitals University Trust (UK)

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

December 2020 to February 2024

Who is funding the study?

AMBU Ltd (UK), Cardiac Remotes Ltd (UK), and the National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
247448

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

CPMS 46556, IRAS 247448

Study information

Scientific Title

The assessment of left ventricular function in septic shock; comparison of ejection fraction measurement (both by two dimensional and three dimensional echocardiography), global longitudinal strain, high sensitivity troponin and pro NtBNP.

Acronym

GLASSheart

Study objectives

1. To extend knowledge since re-classification of sepsis and septic shock (Sepsis 3 criteria)
2. To improve early diagnosis of septic cardiomyopathy in the critical care population using newer echocardiographic techniques such as Global Longitudinal Strain (GLS)
3. To investigate if decreased GLS can identify patients who are at risk of progressive left ventricular dysfunction (assessed by echocardiogram at 90 days) and major adverse cardiovascular events (assessed at 1 year)
4. To evaluate whether established biomarkers add additional clinical utility.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/10/2020, East of England – Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS; +44 (0)2071048384; cambridgecentral.rec@hra.nhs.uk), ref: 20/EE/0209

Study design

Non-randomized cohort study

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Left ventricular function in septic shock

Interventions

GLASSheart is a cohort study. Within the first 24 h, the study team will obtain consent to participate and then start to collect demographic and basic physiological data from participants (this data is standard routine care for the monitoring of the critically unwell patient) including ventilator settings, estimated or actual weight, urine analysis, ECG (electrical tracing of heart activity), and blood pressure and vital signs.

The study data collection of 2D echo, 3D echo, GLS, and both biomarker blood tests are additional procedures/tests and occur in the following time periods:

1. 1st scan at 24 h including echo scans (2D, 3D, and GLS) and blood tests (high sensitivity Troponin and Pro NT BNP)
2. 2nd scan at 48-72 h including repeat echo scans (2D, 3D, and GLS) only
3. 3rd scan at 30 days (+/- 5 days) including repeat echo scans (2D, 3D, and GLS) and blood tests (high sensitivity Troponin and Pro NT BNP)
4. 4th Scan at 90 days (+/- 5 days) including repeat echo scans (2D, 3D, and GLS) and blood tests (high sensitivity Troponin and Pro NT BNP)

It is assumed that most participants will have been discharged from critical care by ≥ 30 days. In this case, they will be contacted by telephone to be offered follow-up appointments for the 3rd and 4th scans and blood tests. If participants remain within the hospital at 30 and 90 days, then the assessment can be done in the hospital.

Intervention Type

Other

Primary outcome(s)

1. Left ventricular function measured using:
 - 1.1. Echocardiography: two-dimensional ejection fraction calculation (2D EF), three-dimensional ejection fraction (3D EF), and global longitudinal strain (GLS), at 24 h, 72 h, 30 days, and 90 days
 - 1.2. Peripheral venous blood tests to identify troponin (high sensitivity assay- HS TROP), and B-type natriuretic peptides (BNP) at 24 h, 30 days, and 90 days

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

29/02/2024

Eligibility

Key inclusion criteria

1. Aged 18-85 years inclusive
2. Sepsis or septic shock (defined by Third International Consensus Definitions for Sepsis and Septic Shock)
3. Admission to the Intensive Care Unit (ICU)
4. Consent to inclusion or favourable opinion for inclusion from consultee

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Total final enrolment

118

Key exclusion criteria

1. Pregnancy or complications thereof
2. End-Stage Renal Failure (ESRF) requiring dialysis, or Chronic Kidney Disease (CKD) with eGFR <30 ml/min
3. Cardiac transplant recipient
4. Uncorrected valvular dysfunction (graded as moderate or severe)
5. Known structural heart disease
6. Pre-existing cardiomyopathy with bundle block on electrocardiogram (ECG)
7. Previous cardiac valve replacement
8. Post-operative within last 7 days
9. Atrial fibrillation/flutter or frequent ventricular ectopic beats during image acquisition
10. Death likely within 24 h in the opinion of the assessing clinician

Date of first enrolment

01/04/2021

Date of final enrolment

28/02/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Portsmouth Hospitals NHS Trust

De La Court House

Queen Alexandra Hospital

Southwick Hill Road

Portsmouth

United Kingdom

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Sponsor information

Organisation

Portsmouth Hospitals NHS Trust

ROR

<https://ror.org/009fk3b63>

Funder(s)**Funder type**

Industry

Funder Name

AMBU Ltd

Funder Name

National Institute for Health Research (NIHR) (UK)

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

Cardiac Remotes Ltd

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v3.0		07/12/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.0	01/06/2020	07/12/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes