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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	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/12/2020	**Overall study status** Completed	
Last Edited 11/05/2023	**Condition category** Circulatory System	

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?
Mrs Emma Lane
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Study website
http://www.GLASSheartstudy.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
247448

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional file ISRCTN13837507_PIS_v3.0

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2018

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
Planned Sample Size: 108; UK Sample Size: 108

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
England

United Kingdom

Study participating centre
Portsmouth Hospitals NHS Trust
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Queen Alexandra Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2024

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?
Participant information sheet	version v3.0		07/12/2020	No	Yes
Protocol file	version v1.0	01/06/2020	07/12/2020	No	No
HRA research summary			28/06/2023	No	No