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Measuring levels of inflammation in patients with heart failure and how they relate to heart function and quality of life

Submission date
13/07/2022

Recruitment status
No longer recruiting

Registration date
15/07/2022

Overall study status
Completed

Last Edited
25/11/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Although medical advances have led to improvements in treatments for some types of heart failure, there are still many things we can improve to help patients live longer, prevent hospital admissions, and improve quality of life. Previous studies have suggested that high levels of inflammation might either cause HF or lead to worse symptoms in patients with HF. Levels of inflammation in the bloodstream are regulated by a number of different substances. One of these is a group of substances called salt-inducible kinases (SIKs). In this study, we are going to find out whether levels of SIK activity are related to heart muscle structure and function and symptoms of HF.
If we can understand relationship between SIK activity and inflammation in HF, we could potentially develop new, much needed treatments to improve patients' lives.
We plan to recruit 100 HF patients. We will collect detailed clinical information and blood samples from patients who have consented to participate. This type of study is particularly important as we plan to study a variety of patients with HF, rather than limiting to certain groups, to get a "real-world" picture of how heart failure affects patients.

Who can participate?
Patients with a diagnosis of heart failure.

What does the study involve?
• A blood sample (of approximately 50mls, or 5 tablespoons).
• A heart scan (echocardiogram, an ultrasound test).
• A questionnaire about how your life is impacted by heart failure.
• Allow us to record your past medical history and blood results.
• Allow us to follow up your clinical care by review of relevant medical records.

These tests will be performed at the first visit. For in-patients, we will perform 2 blood tests one within 48 hours of your admission and one at 5 days (or prior to discharge if you are discharged before 5 days). Out-patients will have one sample.

40 patients will be recalled for another blood test at 6 months depending on the level of inflammation on the first blood test.

What are the possible benefits and risks of participating?
Benefits: We already know that heart failure is a major public health issue worldwide. There may not be any direct benefits to you immediately from taking part in the study, however the information we obtain will be useful for us to understand the problems patients with heart failure have. In future we any study findings we make might be useful in understanding why heart failure develops and in developing new treatments for heart failure. These results will be of interest to those involved in providing healthcare and may influence the way we use existing treatments and the advice we give. If we do identify something that may impact on your clinical care we will tell you and your clinician immediately. We will also cover reasonable travel expenses. If you are interested we will send you a summary of the full study results by email or post – please let us know at any point.
Risks: The standard technique for taking blood would be used and if you have given blood before, you will know that you may experience some brief discomfort and/or bruising at the site. You may well also have had an echo scan before. It can sometimes be a little uncomfortable as we occasionally need to press on your chest with the probe to get good pictures, but generally, patients also manage this without any problems.

Where is the study run from?
Ninewells Hospital, Dundee (UK)

When is the study starting and how long is it expected to run for?
April 2022 to December 2023

Who is funding the study?
Tenovus Scotland (UK)

Who is the main contact?
Dr Ify Mordi, i.mordi@dundee.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
304359

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2-012-22, IRAS 304359, CPMS 51422

Study information

Scientific Title
Inflammation and Salt-inducible kinases - a potential novel therapeutic strategy in patients with heart failure

Acronym
SIK-HF

Study objectives
1. To determine whether levels of systemic inflammation and SIK activity are related to cardiac structural, functional parameters, and quality of life in patients with heart failure.
Hypothesis: Higher levels of systemic inflammation are associated with greater severity of HF, judged by more cardiac structural and functional abnormalities and worse quality of life than those with lower levels of inflammation.
2. To assess, in an ex-vivo study in patients with HF, whether SIK inhibition is associated with a reduction in inflammation, potentially supporting this as a novel therapeutic strategy in patients with HF.
Hypothesis: SIK inhibition is associated with a reduction in markers of inflammation in HF patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/06/2022, East of Scotland Research Ethics Service (Tayside medical science centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 1382 383871; tay.eosres@nhs.scot), ref: 22/ES/0019

Study design
Single-centre observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Heart failure

Interventions
Blood samples, echocardiography and a quality of life questionnaire will be performed in all patients at baseline. Hospitalised patients will have blood sampling performed at 5 days (or on the day of discharge if earlier). A subset of patients will be recalled for further blood sampling, questionnaire and echocardiography at 6 months.

Intervention Type
Other

Primary outcome(s)
Level of SIK activity measured by blood test at baseline

Key secondary outcome(s))
At baseline:
1. Other blood markers of inflammation (interleukins 1-beta, 6 and 10, C-reactive protein)
2. Quality of life measured by the Kansas City Cardiomyopathy Questionnaire
3. Left ventricular ejection fraction measured by echocardiography

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adults (>18 years)
2. Diagnosis of heart failure (stage B or stage C)
3. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
77

Key exclusion criteria
Unable or unwilling to give consent

Date of first enrolment
20/07/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name

Tenovus

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
i.mordi@dundee.ac.uk
Deidentified study data upon submission of a scientific request for further analyses/study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version 2024	16/11/2024	25/11/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1	13/04/2022	14/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	13/04/2022	14/07/2022	No	No