ISRCTN56383403 https://doi.org/10.1186/ISRCTN56383403

Small vessel assessment to guide early hospital discharge following acute heart attack

Submission date
11/06/2024

Recruitment status
Recruiting

Registration date
05/07/2024

Overall study status
Ongoing

Last Edited
02/09/2024

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients presenting with heart attack remain in hospital for 48 hours following their emergency treatment with stents. Recent UK data highlighted the safety of shorter in-hospital stays following heart attacks. Nonetheless, the decision to early discharge patients remains subjective. Index microcirculatory resistance (IMR) is a well-established wire-based technology and can directly evaluate the status of the injured heart immediately after a heart attack. It was demonstrated to be a reliable tool in predicting in-hospital complications and outperformed guidelines-recommended models in identifying patients who are susceptible to adverse outcomes whilst in hospital. IMR is strongly linked to the amount of clot inside the heart blood vessel. New technologies appear promising in reducing clot volume which could help protect the injured heart after a heart attack. The aim of this study is to evaluate the effect of using IMR to guide hospital discharge and its impact on the strength of heart muscle in patients presenting with heart attack.

Who can participate?
Patients aged 18-90 years with acute heart attack

What does the study involve?
Patients who have large clot volumes will be randomly allocated to either a new clot removal device or conventional treatment. The amount of clot will be assessed using an established imaging device and IMR will be performed at the end of the stenting procedure. Patients with favourable IMR will be randomly allocated to early or standard discharge. Patients in the standard discharge will remain in hospital according to local policy. Patients in the early discharge group will be planned for hospital discharge on the following day. Patients with unfavourable IMR will remain in-hospital according to local policy. The strength of the heart muscle is assessed by an MRI scan after 3 months. The amount of clot inside the heart blood vessel is also measured.

What are the possible benefits and risks of participating?
The benefits are identifying patients who are at low risk and suitable for early hospital discharge. The risk is related to early discharge as it is not yet standard clinical practice.

Where is the study run from?
Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2022 to December 2026

Who is funding the study?
1. Abbott Vascular (USA)
2. Vesalio (USA)

Who is the main contact?
Dr Mohammad Alkhalil, mohammad.alkhalil@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Mohammad Alkhalil

ORCID ID
https://orcid.org/0000-0002-3088-8878

Contact details
Cardiothoracic Department
Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 (0)191 233 6161
mohammad.alkhalil@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334935

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10630, IRAS 334935, CPMS 59911

Study information

Scientific Title

Safety of Early discharge Using index microcirculatory Resistance in patients with acute myocardial infarction (SECURE)

Acronym
SECURE

Study objectives
The use of coronary physiology is a safe strategy to guide early discharge in patients presenting with ST-segment elevation myocardial infarction (STEMI)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/04/2024, South East Scotland Research Ethics Committee (Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)7814 764 241; eilidh.clifford@nhs.scot), ref: 23/SS/0116

Study design
Prospective single-centre randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety

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
Acute myocardial infarction

Interventions
The aim of this study is to evaluate the effect of using index microcirculatory resistance (IMR) to guide hospital discharge and its impact on the strength of heart muscle in patients presenting with heart attack. A sub-study of patients who have large clot volume will be randomised, after obtaining verbal consent, to either a new clot removal device or conventional treatment. The amount of clot will be assessed using an established imaging device and IMR will be performed at the end of the stenting procedure. Patients with favourable IMR will be subsequently randomised using web-based randomisation into early or standard discharge. Patients in the standard discharge will remain in the hospital according to local policy. Patients in the early discharge group will be planned for hospital discharge on the following day. Patients with unfavourable IMR will remain in-hospital according to local policy. The primary endpoint of this

study is the strength of the heart muscle as assessed by magnetic resonance imaging after 3 months. For the sub-study, the primary endpoint is the amount of clot inside the heart blood vessel.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Left ventricle function (strength of heart muscle) measured using cardiac magnetic resonance imaging.at 3 months

Secondary outcome measures
1. Clinical events measured using GP/ hospital records and patient contact at 1 year
2. Clot volume during acute heart attack measured using optical coherence tomography at the time of acute heart attack presentation
3. Health status measured using Seattle questionnaire at 3 months

Overall study start date
01/02/2022

Completion date
28/12/2026

Eligibility

Key inclusion criteria
Patients aged 18-90 years presenting with ST-segment elevation myocardial infarction (STEMI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex

Both

Target number of participants
122

Key exclusion criteria
1. Patients in whom safety or clinical concerns preclude participation
2. Pregnant or breastfeeding female
3. Suboptimal angiographic results such as final slow flow or distal embolization
4. Need for in-hospital staged percutaneous coronary intervention (PCI)
5. Cardiogenic shock
6. Pulmonary oedema or severe heart failure requiring diuretics treatment during or immediately after the procedure
7. Contraindication to adenosine
8. Standard contra-indications to MRI such as claustrophobia
9. Known allergy to any other component of xience stent

Date of first enrolment
09/05/2024

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Research Office
Regent Point

Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)1912825490
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Abbott Vascular

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Vesalio

Results and Publications

Publication and dissemination plan
The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the

study was funded by the appropriate funding body. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

Intention to publish date
28/12/2027

Individual participant data (IPD) sharing plan
Data related to this study will be available from Dr Mohammad Alkhalil (mohammad.alkhalil@nhs.net) on reasonable request

IPD sharing plan summary
Available on request