REVascularisation for Ischaemic VEntricular Dysfunction

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
20/11/2012		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/11/2012	Completed	[X] Results		
Last Edited 22/12/2022	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Current plain English summary as of 14/09/2018:

Background and study aims

In 2002, it was estimated that approximately 900,000 individuals in the United Kingdom had a diagnosis of heart failure and at least 1 in 20 of all deaths here were related to this condition. There is evidence of an increase in heart failure in the population, with the number of associated hospital admissions expected to increase by around 50% in the next 25 years. This is the likely consequence of a progressively aging population and improved survival from acute coronary syndromes, partly due to more efficient and timely revascularisation techniques. Patients with heart failure are traditionally treated with a combination of tablets and (in some cases) by insertion of a special pacemaker. Together these treatments are called Optimal Medical Therapy (OMT). In patients who have heart failure as well as narrowed heart arteries, several recent studies have suggested that treatment of the narrowed arteries by Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) may improve heart muscle pumping strength and heart failure symptoms. However, most of these studies have been too small or have not been scientific enough to allow widespread use of PCI or CABG as a treatment for heart failure. The purpose of this study is to assess whether treatment of heart arteries by angioplasty and stenting (PCI) in combination with OMT can improve heart muscle function, quality of life and life expectancy of patients, compared to OMT alone.

Who can participate?

Patients at least 18 years of age with poor heart pumping function and diseased arteries of the heart.

What does the study involve?

Patients will be randomly allocated to two treatment groups - either Percutaneous Coronary Intervention (PCI) and Optimal Medical Therapy (OMT), or to OMT alone.

What are the possible benefits and risks of participating?

As the benefit of treating narrowed arteries has not been clearly established yet, patients should assume that there would be no direct benefit to them. There is a very small risk of major

complications during or shortly after the PCI procedure (including damage to an artery, heart attack, stroke or death). PCI procedures involve exposure to radiation in the form of X-rays, which can potentially be harmful.

Where is the study run from?

The trial will take place at approximately 35 centres in the UK. The main centre is Guy's & St Thomas' NHS Foundation Trust in London and will be coordinated from the London School of Hygiene and Tropical Medicine Clinical Trials Unit (LSHTM CTU).

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

Recruitment began in August 2013 and will continue until the end of April 2020. Follow-up will be for a minimum of two years, and the study is expected to finish in March 2022 (updated 15/06/2021, previously: December 2022.)

Who is the main contact? Ruth Canter ruth.canter@lshtm.ac.uk

Previous plain English summary:

Background and study aims

In 2002, it was estimated that approximately 900,000 individuals in the United Kingdom had a diagnosis of heart failure and at least 1 in 20 of all deaths here were related to this condition. There is evidence of an increase in heart failure in the population, with the number of associated hospital admissions expected to increase by around 50% in the next 25 years. This is the likely consequence of a progressively aging population and improved survival from acute coronary syndromes, partly due to more efficient and timely revascularisation techniques. Patients with heart failure are traditionally treated with a combination of tablets and (in some cases) by insertion of a special pacemaker. Together these treatments are called Optimal Medical Therapy (OMT). In patients who have heart failure as well as narrowed heart arteries, several recent studies have suggested that treatment of the narrowed arteries by Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) may improve heart muscle pumping strength and heart failure symptoms. However, most of these studies have been too small or have not been scientific enough to allow widespread use of PCI or CABG as a treatment for heart failure. The purpose of this study is to assess whether treatment of heart arteries by angioplasty and stenting (PCI) in combination with OMT can improve heart muscle function, quality of life and life expectancy of patients, compared to OMT alone.

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When is study starting and how long is it expected to run for? Recruitment will begin in May 2013 and continue until May 2016. Follow-up will be for a minimum of two years, and the study is expected to finish in May 2018.

Who is funding the study? NIHR Health Technology Assessment - HTA (UK).

Who is the main contact? Richard Evans richard.evans@lshtm.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Type(s)

Public

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT01920048

Protocol serial number

HTA 10/57/67

Study information

Scientific Title

REVascularisation for Ischaemic VEntricular Dysfunction

Acronym

REVIVED

Study objectives

Current study hypothesis as of 21/04/2022:

Compared to medical therapy alone, PCI improves event-free survival in patients with ischaemic cardiomyopathy and viable myocardium.

More details and the latest version of the Protocol can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/105767#/

Previous study hypothesis:

Compared to medical therapy alone, PCI improves event-free survival in patients with ischaemic cardiomyopathy and viable myocardium.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/105767 Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/81124/PRO-10-57-67.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Westminster Research Ethics Committee, 13/09/2010, bref: 10/H0802/46

Study design

Multi-centre phase III randomised double-blind controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiology, heart failure

Interventions

Patients are randomised to receive either Optimal Medical Therapy (OMT) alone or Percutaneous Coronary Intervention (PCI) and OMT.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Current primary outcome measure as of 23/10/2018:

A composite of all-cause death and hospitalisation due to heart failure with a minimum follow-up of 2 years and maximum follow-up of approximately 8.5 years depending on time of randomisation.

Previous primary outcome measure as of 14/09/2018:

A composite of all-cause death and hospitalisation due to heart failure

Previous primary outcome measures:

- 1. All-cause death
- 2. Acute myocardial infarction or hospitalisation due to heart failure (hierarchy: death > MI > heart failure)

Key secondary outcome(s))

Current secondary outcome measures as of 21/04/2022:

- 1. Left Ventricular Ejection Fraction (LVEF) on echocardiography at 6 months and 1 year
- 2. Quality of life score:
- 2.1. Kansas City Cardiomyopathy questionnaire (KCCQ) up to 2 years
- 2.2. EuroQol EQ-5D-5L at 6 months and then yearly to the end of follow-up
- 3. New York Heart Association Functional (NYHA) Class up to 2 years
- 4. Cardiovascular death over the entire duration of follow-up
- 5. All-cause death over the entire duration of follow-up
- 6. Hospitalisation due to heart failure over the entire duration of follow-up
- 7. Acute myocardial infarction (MI) over the entire duration of follow-up
- 8. Appropriate implantable cardioverter defibrillator (ICD) therapy to 2 years
- 9. Unplanned further revascularisation over the entire duration of follow-up
- 10. Canadian Cardiovascular Society (CCS) up to 2 years
- 11. NHS resource use
- 12. Brain natriuretic peptide (BNP or NT-Pro BNP) up to 2 years
- 13. Major bleeding up to 2 years

Previous secondary outcome measures:

- 1. Cardiovascular death, MI, CVA or unplanned revascularisation at 30-days
- 2. Left ventricular ejection fraction at 6 months, 1 year
- 3. Cardiovascular death or myocardial infarction
- 4. Hospitalisation for heart failure
- 5. Appropriate ICD therapy
- 6. Unplanned further revascularisation
- 7. Acute coronary syndrome

Completion date

31/03/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 13/08/2014:

- 1. LVEF ≤35%
- 2. Extensive coronary disease (BCIS-1 Jeopardy Score ≥6)
- 3. Viability in at least 4 dysfunctional segments, that can be revascularised by PCI

Previous inclusion criteria:

- 1. LVEF ≤30%
- 2. Extensive coronary disease (BCIS-1 Jeopardy Score ≥6)
- 3. Viable myocardium in ≥30% of dysfunctional segments

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

700

Key exclusion criteria

Current exclusion criteria as of 14/09/2018:

- 1. Myocardial infarction <4 weeks previously
- 2. Decompensated heart failure requiring inotropic support, invasive or non-invasive ventilation or IABP/left ventricular assist device (LVAD) therapy <72 hours prior to randomisation
- 3. Sustained VT/VF or appropriate ICD discharges <72 hours prior to randomisation
- 4. Valve disease requiring intervention
- 5. Contraindications to PCI
- 6. Aged <18 years
- 7. eGFR < 25 ml/min, unless established on dialysis
- 8. Women who are pregnant
- 9. Previously enrolled in REVIVED-BCIS2 or current enrolment in other trial that may affect REVIVED-BCIS2 outcome data
- 10. Life expectancy <1 year due to non-cardiac pathology

Previous exclusion criteria as of 13/08/2014:

Specific exclusions:

- 1. Significant angina (≥CCS class 3)
- 2. Myocardial infarction < 4 weeks previously

General exclusions:

- 1. Decompensated heart failure requiring inotropic support or IABP/LVAD therapy <72 hours prior to randomisation
- 2. Sustained VT/VF or appropriate ICD discharges <72 hours prior to randomisation
- 3. More than mild aortic stenosis or more than mild aortic regurgitation on echocardiography
- 4. Contra-indications to PCI
- 5. Age <18 years
- 6. eGFR < 25 ml/min, unless established on dialysis
- 7. Women who are pregnant
- 8. Previously enrolled in REVIVED or current enrolment in other study
- 9. Life expectancy < 1 year due to non-cardiac pathology

Previous exclusion criteria:

Specific exclusions:

- 1. Significant angina (≥CCS class 3)
- 2. Myocardial infarction < 6 weeks previously

General exclusions:

- 1. Decompensated heart failure requiring inotropic support or IABP/LVAD therapy <72 hours prior to randomisation
- 2. Sustained VT/VF or appropriate ICD discharges <72 hours prior to randomisation
- 3. More than mild aortic stenosis or mild aortic regurgitation on echocardiography
- 4. Contra-indications to PCI, including contra-indications to Aspirin or Clopidogrel or Heparin
- 5. Age <18 years
- 6. Bleeding diathesis or Warfarin therapy with INR>3
- 7. Active internal bleeding (except menstruation)
- 8. Platelet count < 100,000 cells/mm3) at randomisation
- 9. Haemoglobin < 9 g/dl at randomisation
- 10. eGFR < 25 ml/min, unless established on dialysis
- 11. Women who are pregnant
- 12. Previously enrolled in REVIVED or current enrolment in other study
- 13. Life expectancy < 1 year due to non-cardiac pathology

Date of first enrolment

01/08/2013

Date of final enrolment

19/03/2020

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre King's College London

London United Kingdom SE5 9RS

Study participating centre Basingstoke and North Hampshire Hospital Basingstoke

United Kingdom RG24 9NA

Study participating centre Blackpool Victoria Hospital Blackpool United Kingdom FY3 8NR

Study participating centre Derriford Hospital Plymouth United Kingdom PL6 8DH

Study participating centre
Dorset County Hospital
Dorchester
United Kingdom
DT1 2JY

Study participating centre Freeman Hospital Newcastle United Kingdom NE7 7DN

Glan Clwyd Hospital

North Wales Cardiac Centre Rhyl United Kingdom LL30 1LB

Study participating centre Glenfield Hospital

Leicester United Kingdom LE3 9QP

Study participating centre Golden Jubilee National Hospital

Glasgow United Kingdom G81 4DY

Study participating centre Great Western Hospital

Swindon United Kingdom SN3 6BB

Study participating centre Kettering General Hospital

Kettering United Kingdom NN16 8UZ

Study participating centre Leeds General Infirmary

Leeds United Kingdom LS1 3EX

Study participating centre Lister Hospital Stevenage

United Kingdom SG1 4AB

Study participating centre
Liverpool Heart and Chest Hospital
Liverpool
United Kingdom
L14 3PE

Study participating centre Manchester Royal Infirmary Manchester United Kingdom M13 9WL

Study participating centre New Cross Hospital Wolverhampton United Kingdom WV10 0QP

Study participating centre Ninewells Hospital Dundee United Kingdom DD1 9SY

Study participating centre Pinderfields Hospital Wakefield United Kingdom WF1 4DG

Study participating centre Queen Alexandra Hospital Portsmouth United Kingdom PO6 3LY

Study participating centre Royal Bournemouth Hospital

Bournemouth United Kingdom BH7 7DW

Study participating centre Royal Devon and Exeter Hospital

Exeter United Kingdom EX2 3DW

Study participating centre Royal Free Hospital

London United Kingdom NW3 2PF

Study participating centre Royal Infirmary of Edinburgh

Edinburgh United Kingdom EH16 4SA

Study participating centre Royal Oldham Hospital

Oldham United Kingdom OL1 2JH

Study participating centre Royal Victoria Hospital

Belfast United Kingdom BT12 6BA

Study participating centre

Salisbury District Hospital

Salisbury United Kingdom SP2 8BJ

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre St Bartholomew's Hospital London United Kingdom EC1A 7BE

Study participating centre St George's Hospital London United Kingdom SW17 0QT

Study participating centre St Thomas' Hospital London United Kingdom SE1 7EH

Study participating centre Sunderland Royal Hospital Sunderland United Kingdom SR4 7TP

Study participating centre

The James Cook University Hospital

Middlesbrough United Kingdom TS4 3BW

Study participating centre University Hospital Coventry

Coventry United Kingdom CV2 2DX

Study participating centre Worcestershire Royal Hospital

Worcester United Kingdom WR5 1DD

Study participating centre Worthing Hospital

Worthing United Kingdom BN11 2DH

Study participating centre Wythenshawe Hospital

Manchester United Kingdom M23 9QZ

Study participating centre Bristol Royal Infirmary

Upper Maudlin Street Bristol United Kingdom BS2 8HW

Study participating centre Birmingham Heartlands Hospital Birmingham

Study participating centre York HospitalYork

United Kingdom YO31 8HE

Study participating centre Northern General Hospital Sheffield United Kingdom S5 7AU

Sponsor information

Organisation

King's College London

ROR

https://ror.org/0220mzb33

Organisation

Guy's and St Thomas' NHS Foundation Trust

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment - HTA (UK), ref: 10/57/67

Results and Publications

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?
Results article	primary composite outcome of death from any cause or hospitalization for heart failure	13/10 /2022	22/12 /2022	Yes	No
Protocol article	protocol	01/06 /2018	19/11 /2019	Yes	No
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes