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REVascularisation for Ischaemic VEntricular Dysfunction

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

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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Where is the study run from?
The trial will take place at approximately 25 centres in the UK. The main centre is Guy's & St Thomas' NHS Foundation Trust in London and will be coordinated from the clinical trial unit at London School of Hygiene and Tropical Medicine (UK).

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

Study website
http://revived.lshtm.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01920048

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/05/2013

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

Age group
Adult

Sex
Both

Target number of participants
700

Total final enrolment

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
England

Northern Ireland

Scotland

United Kingdom

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

Study participating centre
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
United Kingdom
B9 5SS

Study participating centre
York Hospital
York
United Kingdom
YO31 8HE

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

Sponsor information

Organisation
King's College London

Sponsor details
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reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy’s and St Thomas’ NHS Foundation Trust

Sponsor details
St Thomas' Hospital
Westminster Bridge Rd
Lambeth
London
England
United Kingdom
SE1 7EH
-
crf@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan

We plan to publish the trial results in a high-impact peer-reviewed journal and present the results at an international cardiology conference.
We also plan to disseminate the results to the trial participants, recruiting hospitals, relevant PPI groups, and the relevant local, national, and international clinical and regulatory bodies.

Intention to publish date

31/12/2022

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