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Surgical Treatment for Ischaemic Heart Failure Trial (STICH)

Submission date 07/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/07/2010	**Overall study status** Completed	
Last Edited 17/07/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00023595

Protocol serial number
5148

Study information

Scientific Title

Surgical Treatment for Ischaemic Heart Failure Trial (STICH): a multicentre randomised interventional treatment trial

Study objectives
No randomised trial has ever directly compared long-term benefits of surgical and medical treatment of patients with ischaemic heart failure (HF). Along the broad spectrum of severity of ischaemic HF, specific clinical information, such as severe angina or left main coronary artery stenosis, may clearly indicate the need for surgical therapy for some patients.

However, a large number of patients fall into a gray zone without clear evidence for benefit from either medical or surgical therapy. For these patients, evidence supporting choice between therapies was never strong and has only been confused by recent studies showing improved outcomes with both therapies.

Patients for whom equipoise of anticipated benefit now exists between modern medical and surgical therapy represent the broad population who are appropriate candidates for a randomised trial to provide the context for assessing the value of two therapeutic strategies:
1. Medication (MED) alone
2. MED and coronary artery bypass grafting (CABG)

The study is also being run in the USA and includes surgical ventricular reconstruction as a treatment option in those sites only.

As of 13/07/2010 the study is seeking a protocol amendment to extend follow-up for another 9 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding REC, 04/08/2005, ref: 05/MRE00/51

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
1. Optical medication (for heart failure according to National Institute for Clinical Excellence [NICE] guidelines)
2. CABG and optimal medication

Total duration of treatment: up to 6 years maximum
Follow-up length: 36 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
CABG combined with MED compared to MED alone, measured up to 6 years.

Key secondary outcome(s))
Measured up to 6 years:
1. Cardiac magnetic resonance (CMR) of left ventricle (LV) shape, size and function for predicting the benefit of a specific treatment strategy
2. Nuclear cardiology and/or echocardiography testing of myocardial ischaemia

Completion date
30/05/2007

Eligibility

Key inclusion criteria
1. Men
2. Women who are not of childbearing potential
3. Aged 18 years or above
4. Who have a left ventricular ejection fraction (LVEF) less than 0.35 measured by cardiac magnetic resonance (CMR) ventriculogram, gated single photon emission computed tomography (SPECT) ventriculogram, echocardiography, or contrast ventriculogram within three months of trial entry
5. Who have coronary artery disease suitable for revascularisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Failure to provide informed consent
2. Aortic valvular heart disease clearly indicating the need for aortic valve repair or replacement
3. Cardiogenic shock (within 72 hours of randomization) as defined by the need for intra-aortic balloon support or the requirement for intravenous inotropic support
4. Plan for percutaneous intervention of coronary artery disease
5. Recent acute myocardial infarction judged to be an important cause of left ventricular dysfunction
6. History of more than one prior coronary bypass operation
7. Non-cardiac illness with a life expectancy of less than 3 years
8. Non-cardiac illness imposing substantial operative mortality
9. Conditions/circumstances likely to lead to poor treatment adherence (e.g., history of poor compliance, alcohol or drug dependency, psychiatric illness, no fixed abode)
10. Previous heart, kidney, liver, or lung transplantation
11. Current participation in another clinical trial in which a patient is taking an investigational drug or receiving an investigational medical device

MED Therapy Eligibility Criteria:
12. Absence of left main coronary artery disease as defined by an intraluminal stenosis of 50% or greater
13. Absence of Canadian Class III angina or greater (angina markedly limiting ordinary activity)

Date of first enrolment
22/12/2005

Date of final enrolment
30/05/2007

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
Department of Cardiology
Cottingham
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Sponsor information

Organisation
Duke University (USA)

ROR
https://ror.org/00py81415

Funder(s)

Funder type
Government

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
National Institutes of Health (NIH) (USA) - National Heart, Blood and Lung Institute (ref: 5 U01 HL069015-4)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/04/2009		Yes	No
Results article	results	01/05/2009		Yes	No
	results				

Results article		03/08/2010		Yes	No
Results article	results	03/08/2010		Yes	No
Results article	results	28/04/2011		Yes	No
Results article	results	28/04/2011		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	29/05/2012		Yes	No
Results article	results	01/01/2013		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	07/05/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/11/2013		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	01/08/2014		Yes	No
Protocol article	protocol	01/12/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes