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Arterial Revascularisation Trial - a randomised trial to compare survival following bilateral versus single internal mammary artery (IMA) grafting in coronary revascularisation

Submission date
19/10/2004

Recruitment status
No longer recruiting

Registration date
17/01/2005

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Circulatory System

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

Plain English Summary

Current plain English summary as of 26/10/2021:
Background and study aims
A coronary artery bypass graft (CABG) is a surgical procedure that diverts blood around narrowed or clogged arteries of the heart to improve blood flow and oxygen supply to the heart. CABG surgery provides excellent short- and intermediate-term success in treating coronary heart disease but its long-term success may be limited by failure of the veins that have been used to bypass the blood vessels of the heart. Ten years after CABG, around ½ of vein grafts have become blocked or diseased although current drug therapy such as aspirin and statins (which lower cholesterol) may reduce this failure. Blocked or diseased vein grafts means that the patient may develop recurrent angina (chest pain) and may require further treatment including the possibility of another operation. The artery grafts last better than the vein grafts. There is some circumstantial (but no definite) evidence that if both of the mammary arteries are used in the CABG operation instead of just one it may improve the longer-term outcome. The aim of this study is to determine if the use of both mammary arteries improves survival, and reduces the chance of recurrent angina and/or the need for further intervention (including surgery) compared to using one mammary artery. Patients will be followed up for 15 years after surgery.

Who can participate?
CABG patients with coronary heart disease.

What does the study involve?
Patients are randomly allocated to receive either a single internal mammary artery (SIMA) graft or a bilateral internal mammary artery (BIMA) graft during their CABG surgery. Patients are then followed up every year for up to 10 years after their surgery to collect data on their health status and quality of life, and then again at 15 years after surgery to determine their health status.
What are the possible benefits and risks of participating?
The possible disadvantages and risks of taking part are common to all patients undergoing CABG

surgery. The possible disadvantages of BIMA grafting is that there may be a slightly increased risk of poor wound healing. The risk of poor wound healing with the standard SIMA operation is 1%-2% and this may increase by a further 1% in the BIMA group. However, this is usually only a problem in those with diabetes, or who are already very overweight or have severe breathing problems. A further consideration is that BIMA grafting has a slightly longer operation time (approximately 30 minutes in a three hour procedure) than SIMA grafting. Patients taking part in the study will be asked to complete quality of life questionnaires which may be regarded by some as an inconvenience. Both the SIMA grafting and the BIMA grafting should help treat the patient's coronary heart disease. The possible advantages of BIMA grafting are that there may be a reduced risk of angina, heart attack and a requirement for further intervention, including the possibility of a second CABG operation in the long term. It is not possible to say definitively which type of grafting is better but the information from this study should help to decide the best treatment in the future for patients with coronary heart disease.

Where is the study run from?
Department of Cardiothoracic Surgery, The John Radcliffe (UK)

When is the study starting and how long is it expected to run for?
July 2004 to December 2023

Who is funding the study?
1. British Heart Foundation (UK) up to the 15-year follow up
2. Medical Research Council (UK) up to the 10-year follow up

Who is the main contact?
Prof. David Taggart
David.Taggart@ouh.nhs.uk

Background and study aims
A coronary artery bypass graft (CABG) is a surgical procedure that diverts blood around narrowed or clogged arteries of the heart to improve blood flow and oxygen supply to the heart. CABG surgery provides excellent short and intermediate term success in treating coronary heart disease but its long-term success may be limited by failure of the veins that have been used to bypass the blood vessels of the heart. Ten years after CABG, around ½ of vein grafts have become blocked or diseased although current drug therapy such as aspirin and statins (which lower cholesterol) may reduce this failure. Blocked or diseased vein grafts means that the patient may develop recurrent angina (chest pain) and may require further treatment including the possibility of another operation. The artery grafts last better than the vein grafts. There is some circumstantial (but no definite) evidence that if both of the mammary arteries are used in the CABG operation instead of just one it may improve the longer-term outcome. The aim of this study is to determine if the use of both mammary arteries improves survival, and reduces the chance of recurrent angina and/or the need for further intervention (including surgery) compared to using one mammary artery. Patients will be followed up for 10 years after surgery.

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What does the study involve?
Patients are randomly allocated to receive either a single internal mammary artery (SIMA) graft or a bilateral internal mammary artery (BIMA) graft during their CABG surgery. Patients are then followed up every year for up to 10 years after their surgery. Data is collected on their health status and quality of life.

What are the possible benefits and risks of participating?
The possible disadvantages and risks of taking part are common to all patients undergoing CABG surgery.The possible disadvantages of BIMA grafting is that there may be a slightly increased risk of poor wound healing. The risk of poor wound healing with the standard SIMA operation is 1%-2% and this may increase by a further 1% in the BIMA group. However, this is usually only a problem in those with diabetes, or who are already very overweight or have severe breathing problems. A further consideration is that BIMA grafting has a slightly longer operation time (approximately 30 minutes in a three hour procedure) than SIMA grafting. Patients taking part in the study will be asked to complete quality of life questionnaires which may be regarded by some as an inconvenience. Both the SIMA grafting and the BIMA grafting should help treat the patient's coronary heart disease. The possible advantages of BIMA grafting are that there may be a reduced risk of angina, heart attack and a requirement for further intervention, including the possibility of a second CABG operation in the long term. It is not possible to say definitively which type of grafting is better but the information from this study should help to decide the best treatment in the future for patients with coronary heart disease.

Where is the study run from?
Department of Cardiothoracic Surgery, The John Radcliffe (UK)

When is the study starting and how long is it expected to run for?
July 2004 to June 2014

Who is funding the study?
1. British Heart Foundation (UK)
2. Medical Research Council (UK)

Who is the main contact?
Prof. David Taggart
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Study website
https://www.situ.ox.ac.uk/surgical-trials/art

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0200390

Study information

Scientific Title
Arterial Revascularisation Trial - a randomised trial to compare survival following bilateral versus single internal mammary artery (IMA) grafting in coronary revascularisation

Acronym
ART

Study hypothesis
The main objective is to assess whether the use of both IMA during coronary artery bypass graft (CABG) surgery improves survival and reduces the need for further interventions over that observed with a single IMA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 26/10/2021:
Approved 09/04/2004, amendment for 15 year follow-up approved 13/12/19, HRA North East-York (NHSBT, Newcastle Blood Donor Centre, Holland Drive, HRA Jarrow, NE2 4NQ; +44 (0)207 104 8079; nrescommittee.northeast-york@nhs.net), ref: 04/3/006

Previous ethics approval:
HRA North East-York, 09/04/2004, ref: 04/3/006

Study design
Randomised 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 to request a patient information sheet

Condition
Cardiovascular

Interventions
Current interventions as of 26/10/2021:
Patients were randomised to single internal mammary artery (SIMA) grafting or bilateral internal mammary artery (BIMA) grafting with supplemental vein or radial artery grafts as required. Patients will be followed-up for up to 15 years.

Previous interventions:
Patients will be randomised to single internal mammary artery (SIMA) grafting or bilateral internal mammary artery (BIMA) grafting with supplemental vein or radial artery grafts as required.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 26/10/2021:
Survival will be measured using patient telephone follow-up or by national databases where applicable at 10 and 15 years.

Previous primary outcome measure:
Survival

Secondary outcome measures
Current secondary outcome measures as of 26/10/2021:
1. Cause-specific mortality measured using patient telephone follow-up or by national databases where applicable at 10 and 15 years
2. Major Adverse Cardiovascular Events measured using patient telephone follow-up or by national databases where applicable at 15 years
3. 30 day mortality measured using patient telephone follow-up or by national databases where applicable at 30 days
4. Need for re-intervention by percutaneous coronary intervention or redo surgery other clinical events measured using patient telephone follow-up or by national databases where applicable at 10 years
5. Quality of life measured using the Short Form-36 (SF36), Rose, and EuroQol questionnaires at 10 years
6. Cost-effectiveness measured using patient telephone follow-up or by national databases where applicable at 10 years

Previous secondary outcome measures:
1. Cause-specific mortality
2. 30 day mortality
3. Need for re-intervention by percutaneous coronary intervention or redo surgery
other clinical events
4. Quality of life (SF36, Rose and EuroQol)
5. Cost-effectiveness

Overall study start date
01/07/2004

Overall study end date
31/12/2023

Eligibility

Participant inclusion criteria
Coronary artery bypass graft (CABG) patients with multi-vessel coronary artery disease (including urgent and off pump CABG patients)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3000

Total final enrolment
3102

Participant exclusion criteria
1. Single graft
2. Redo CABG
3. Evolving myocardial infarction
4. Concomitant valve surgery

Recruitment start date
01/07/2004

Recruitment end date
20/12/2007

Locations

Countries of recruitment
Australia

Austria

Brazil

England

India

Italy

Poland

United Kingdom

Study participating centre
Department of Cardiothoracic Surgery, The John Radcliffe
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865 270000
B.Lees@rbh.nthames.nhs.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
British Heart Foundation (SP/03/001)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Medical Research Council (G0200390)

Alternative Name(s)
UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The 10 year outcomes of ART have been published and the 15 year outcomes will be published in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Anonymised datasets available by request to the Chief Investigator, Professor David Taggart (David.Taggart@ouh.nhs.uk) on behalf of the ART Trial Management Group once the study has been completed and published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/03/2006		Yes	No
Results article	results	01/10/2010		Yes	No
Other publications	assessment of data quality	26/09/2011		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	29/12/2016		Yes	No
Results article	results	01/08/2017		Yes	No
Results article	results	01/11/2017		Yes	No
Results article	results	03/03/2018		Yes	No
Results article	results	31/01/2019		Yes	No
Results article	results	01/08/2019	11/06/2020	Yes	No