

December 2017

Welcome to the Patient Newsletter for the ART trial

Firstly, may we take this opportunity to thank you again for your generous support and participation in ART. As you know, we are following you up for 10 years after your CABG surgery. Some of you will have already completed your 10 year follow up but the follow up of all patients participating in ART will not be complete until the summer. The main findings will not be available until early 2018.

In the meantime, however, your participation has already enabled us to answer some important questions regarding patients who undergo coronary artery bypass graft (CABG) surgery.

For example, we have recently published the results of the 5 year follow up data in a leading medical journal: the "New England Journal of Medicine". For those of you who have access to the internet the reference to the article published in the New England Journal of Medicine is below:

"Randomized Trial of Bilateral versus Single Internal-Thoracic-Artery Grafts".
New England Journal of Medicine. 2016 Dec 29; 375(26):2540-9 Taggart DP, Altman DG, Gray AM, Lees B, Gerry S, Benedetto U, Flather M; ART Investigators.

For those of you who don't have access to the internet, the main findings of the study so far can be summarised as follows:

- **Excellent 5 year results for coronary artery bypass surgery (CABG) in both the single internal mammary artery group (SIMA) and the bilateral (double) internal mammary artery group (BIMA)**
- **Confirmation of the safety of using bilateral internal mammary artery grafts (BIMA) over the medium term (5-10years)**
- **No significant differences between the two procedures in either survival, heart attack or stroke.**
- **No significant differences in major bleeds, need for repeat CABG surgery, angina status and quality-of-life.**
- **More sternal wound problems after the operation with those receiving bilateral internal mammary artery grafts (BIMA) but these were mainly in diabetic patients and those who were overweight**

Summary of the ART trial

What is the main aim of the ART trial?

The main aim of the ART trial is to determine if the use of both mammary arteries during Coronary Artery Bypass Graft (CABG) surgery improves survival.

What is the procedure that is being tested?

The procedure being tested is the standard Single Internal Mammary Artery (SIMA) graft versus Bilateral Internal Mammary Artery (BIMA) grafts in Coronary Artery Bypass Graft (CABG) surgery. The possible advantages of Bilateral Internal Mammary Artery (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 therefore possible to say definitively which type of grafting is better for you but the information we get from this study may help us to decide the best treatment in the future for patients with coronary heart disease.

What is the purpose of the study?

Coronary artery bypass grafting (CABG) is well established as the best treatment for those with **multiple** diseased blood vessels of the heart (coronary heart disease). Most patients undergoing CABG require 3 new blood vessels (grafts). The standard operation, used in 80%-90% of all patients, is to use **one** of the mammary arteries (from inside the chest) and additional veins from the leg or an artery from the arm. CABG provides excellent short and intermediate term success 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 1/2 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. Using both mammary arteries is a slightly more complex operation, takes an extra half-hour to do and may lead to a small increase in healing problems of the chest wound.

The aim of the ART 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 are being followed up for 10 years after surgery.

Who has reviewed the study?

ART is being led by Professor David Taggart, Consultant Cardiothoracic Surgeon at the John Radcliffe Hospital (University of Oxford). A Steering Committee of experts in heart disease are overseeing the conduct of the study. The study is being co-ordinated by the University of Oxford. ART is being funded jointly by a grant from the British Heart Foundation and a grant from the Medical Research Council and the National Institute for Health Research (NIHR).

National ethics approval has been obtained for this study and your hospital's Research and Development department have reviewed the study for locality issues.

What will happen to the results of the 10 year follow up?

When the study is completed and the 10 year data are analysed and the findings are published, if you wish, we will send you a summary of the main findings. The results will be presented at medical conferences and published in medical journals. Your identity will not be divulged in any presentation, publication or report.

Important Information

We are grateful to you for your on-going participation in the Arterial Revascularisation Trial (ART).

We would like to inform you of an administrative change to the ART study whereby the central management of the study has moved location from the Royal Brompton Hospital to the Nuffield Department of Surgical Sciences at the University of Oxford.

Please note that this administrative change will not affect your care in any way.

As you know we are tracking your health status for up to 10 years after your cardiac surgery. In accordance with your consent form, your name, address, hospital number and date of birth have been sent to the government department that was previously called the "Office of National Statistics" (ONS) and then called the "Health and Social Care Information Centre" (HSCIC) and is now called "NHS Digital". We would like to confirm that your health status will continue to be tracked for up to 10 years by NHS Digital and this information will now be sent to the ART study team at Oxford. We would also like to confirm that you will not be contacted at any time by NHS Digital.

This information is just for courtesy you do not need to do anything and as stated above it will not change your care in any way. However, if you no longer agree to have your health status tracked by NHS Digital, please contact your ART research nurse (contact details attached) and we will inform the ART study team at Oxford.

Thank you once again for your continuing participation in ART.

ART Study Team at the coordinating centre at the University of Oxford

Jo Cook

Research Nurse

Telephone: (01865) 737910

Email: carol.wallis@nds.ox.ac.uk

Address: Nuffield Department of Surgical Sciences
Level 6, John Radcliffe Hospital,
Headley Way, Headington,
Oxford, OX3 9DU

Professor Taggart

Carol Wallis

Trial Manager

Ed Wyatt

Data Manager

Belinda Lees

Trial Consultant

We wish you all the best for the future and look forward to hearing from you

Many Thanks

Professor Taggart and the ART study team

**Amend with local con-
tact details if desired**