

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: PROACT: Can we prevent chemotherapy-related heart damage in patients with breast cancer?

Full Project Title: Preventing cardiac damage in patients treated for breast cancer: a phase 3 Randomised, Open label, blinded endpoint, superiority trial of enalapril to prevent Anthracycline-induced CardioToxicity (PROACT).

Name of Researcher: *Recruiting Centre PI to be entered*

Please initial each of the boxes to confirm your agreement

1. I confirm that I have read, or had read to me, and understand the information sheet dated X (version X) for the PROACT trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time from all, or any part, of the trial without giving any reason, without my medical care or legal rights being affected.
3. I agree to my GP being informed of my participation in this trial, and contacted as required during the trial.
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Clinical Trials Unit and by others from the research team including members of trial committees and those responsible for trial oversight, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. I understand that information about me that is relevant to this trial, including my month and year of birth, gender and ethnicity, will leave the Trust. I understand that the trial team will not publish any information that identifies me. I understand that my data will be stored securely and managed confidentially as part of this trial I understand that the research team may keep this information for up to 15 years following the end of the trial before confidentially destroying it.
6. I understand that anonymised copies of my heart scans will be sent for review by an expert team at The James Cook University Hospital. I agree that this can happen.
7. I understand that taking part in this trial means that I have the same chance of receiving enalapril as not receiving it.
8. I understand that if I am of childbearing potential, I need to take adequate contraception and agree not to become pregnant during the course of this trial
9. I agree to take part in the above study.

10. Following the end of the trial, I agree that the team can keep my heart scans, and, along with the other data collected on me during the trial, use these for further research for up to 15 years Yes No
11. I agree that the team can collect extra blood samples for future research, and that they can link this information to the data collected on me within the trial. (Please initial your choice into the Yes or No boxes. If you initial No, you can still participate in the trial). Yes No
12. I agree that the team can collect a DNA swab from inside my mouth for future research, and that they can link this information to the data collected on me within the trial. (Please initial your choice into the Yes or No boxes. If you initial No, you can still participate in the trial). Yes No
13. I agree that following the end of the trial, the research team can contact me again in the future to follow up my progress and to invite me to have further heart scans. (Please initial your choice into the Yes or No boxes. If you initial No, you can still participate in the trial). Yes No

Name of participant Date Signature

Name of person taking consent Date Signature