

Efficacy of advanced semi-automated functional magnetic resonance (MR) imaging in the early prediction of response of locally advanced breast cancer to neoadjuvant chemotherapy

Submission date 09/04/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/06/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 27/07/2022	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-MRI-scans-during-chemotherapy-before-surgery-for-breast-cancer-neo-comice-pilot-trial>

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00978770

Protocol serial number

Study information

Scientific Title

Establishing the efficacy of advanced semi-automated functional magnetic resonance (MR) imaging in the early prediction of response of locally advanced breast cancer to neoadjuvant chemotherapy: a pilot study

Acronym

Neo-COMICE

Study objectives

This proposal aims to evaluate quantitative functional magnetic resonance imaging (MRI) as an early in-vivo surrogate biomarker. Chemotherapy either directly or indirectly results in a reduction in tumour vascularity and as a consequence quantitative analysis of dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) should be predictive of response to neoadjuvant chemotherapy (NAC) and should not be treatment specific. It is essential that functional MR is compared with other markers of treatment response, namely molecular diagnostic pathology, to enable integration and potential identification of additional prognostic and predictive indicators, and this comparison will be included in a full trial that would follow this feasibility study.

It is anticipated that a subsequent multicentre trial will require around 1300 patients using standardised scan protocols and analytical techniques to provide the statistical robustness that will allow the demonstration of statistical significant changes. In preparation for such a multicentre approach, this feasibility study will use multi-parameter, easily deliverable, protocols applicable to all MR manufacturers; to ensure system stability using phantoms; evaluate the logistics of data transfer and compatibility with study software (MATLAB platform); and analyse data off-line using semi-automated segmentation techniques including Otsu's algorithm, iterative thresholding processes, edge detection and active contouring in order to extract tumour volume, and functional and textural parameters.

Quality assurance of tumour volume determination will be performed using manual contouring as the gold standard. Use of semi-automated techniques for large volume MR data analysis have already been implemented to good effect using Otsu's algorithm and other iterative techniques for delineating bone trabeculations, obtaining grey-white matter segmentation and breast lesion classification. The applicability of these techniques to breast tumour analysis by MR has been reported and critically reviewed.

The main study will require some 1300 patients, recruited from at least 60 centres, using different MRI systems, with the data being analysed centrally using semi-automated techniques. Prior to commencing the main study, the Neo-COMICE pilot study needs to be completed to test the technical feasibility of the main study, i.e. can we reliably, in a multicentre setting using different types of MRI systems, complete MRI scans to protocol, and analyse these centrally using semi-automated techniques?

This pilot study will prospectively recruit 50 patients from different centres, using the most commonly available MR systems for data acquisition, and analyse this data using centralised semi-automated techniques. This will test the technical achievability of producing multi-parameter, multi-MR system standardised protocols, ensuring the compatibility of DICOM

(Digital Imaging and Communications in Medicine) information between MR manufacturers and the use of semi-automated tumour segmentation and analysis tools for data extraction. These quality-assured findings will be used to further develop the MR imaging protocol and inform the subsequent full trial application.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northern and Yorkshire Research Ethics Committee on 02/02/2009 (ref: 08/H0903/73)

Primary study design

Observational

Study design

Phase II multicentre prospective longitudinal observational cohort study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

The trial is anticipated to have an active recruitment period of 14 months. Patients will receive MRI scans at baseline (pre-commencement of chemotherapy), 4 - 7 days after commencement of their first cycle of chemotherapy, at the end of their second cycle of chemotherapy, and at the end of their fourth cycle of chemotherapy. The only follow up data that will be routinely collected is the patients' final pathology report if the patient subsequently undergoes surgery.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

1. The technical feasibility of using MR imaging in a multicentre setting using the most commonly available MR systems (i.e. is the trial able to scan patients to a specific protocol, using different types of MRI machine)
2. How reliably the imaging data can be analysed in a centralised, semi-automated, manner (i.e. can MRI data be reliably transferred from different centres and analysed using software based in the Centre for MR Investigations at the University of Hull)

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/11/2010

Eligibility

Key inclusion criteria

1. Provide written informed consent
2. Female
3. Aged 18 years or over
4. Newly diagnosed, histologically proven breast cancer (TNM stage T2- T4B, N0-3C, and M0)
5. Undergone both x-ray mammography and breast ultrasound scanning during the current treatment episode
6. Scheduled for neo-adjuvant chemotherapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

52

Key exclusion criteria

1. Are medically unstable
2. Previously undergone chemotherapy
3. Have had surgery or radiotherapy for cancer in the ipsilateral breast
4. Have had surgery to the ipsilateral breast within the previous 4 months for benign breast disease
5. Have a history of serious breast trauma within the last 3 months
6. Are pregnant or breast feeding
7. Have renal failure
8. Fail the normal safety requirements of MR, particularly pacemakers and cardiac defibrillators
9. Are known to have had an allergic reaction associated with previous administration of a paramagnetic contrast agent
10. Have a known contraindication to MR scanning
11. Have a disability preventing MR scanning in the prone position
12. Have body habitus incompatible with MR system entry

Date of first enrolment

01/06/2009

Date of final enrolment

01/11/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hull Royal Infirmary

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Hull and East Yorkshire NHS Trust (UK)

ROR

<https://ror.org/01b11x021>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (grant ref: C11421/A9398)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			27/07/2022	No	Yes