ISRCTN42613663 https://doi.org/10.1186/ISRCTN42613663

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

Registration date
17/06/2009

Overall study status
Completed

Last Edited
27/07/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00978770

Secondary identifying numbers
Version 1

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)

Study design
Phase II multicentre prospective longitudinal observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

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

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 measure

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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

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
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire NHS Trust (UK)

Sponsor details
R&D Manager
Second Floor
Daisy Building
Castle Hill Hospital
Cottingham
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

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