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Avastin® Randomised Trial with neo-adjuvant chemotherapy for patients with early breast cancer

Submission date 03/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2009	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/trial-giving-bevacizumab-avastin-chemotherapy-before-surgery-early-her2-negative-breast-cancer-artemis

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01093235

Clinical Trials Information System (CTIS)
2008-002322-11

Study information

Scientific Title
A randomised multicentre phase III prospective open-label trial of pre-operative bevacizumab (Avastin®) in combination with neo-adjuvant chemotherapy for early breast cancer patients

Acronym
ARTemis

Study objectives
A short course of pre-operative bevacizumab (Avastin®) in combination with chemotherapy will improve the pathological complete response to neoadjuvant treatment for HER2-negative breast cancer patients, and thereby improve their chances of breast conservation, as well as improving disease-free and overall survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee (REC), 19/11/2008, ref: 08/H1102/104

Study design
Randomised (1:1) multicentre phase III prospective open-label trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early breast cancer

Interventions
Arm A:
Docetaxel (D) 100 mg/m^2 intravenous (IV) x 3 cycles every 3 weeks (q3w) followed by 5-fluorouracil 500 mg/m^2 IV, epirubicin 100 mg/m^2 IV and cyclophosphamide 500 mg/m^2 (FEC) on day 1 x 3 cycles q3w

Arm B:
Docetaxel (D) 100 mg/m^2 IV x 3 cycles every 3 weeks [q3w] and bevacizumab (Avastin®) 15 mg /kg q3w x 3 cycles followed by FEC plus bevacizumab 15 mg/kg x 1 cycle and three weeks later FEC x 2 cycles q3w

Duration of treatments is 18 weeks. Duration of follow-up is 5 years.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

Bevacizumab (Avastin®), docetaxel, 5-fluorouracil, epirubicin, cyclophosphamide

Primary outcome(s)
Complete pathological response (pathCR) rates (tumour and lymph nodes) after neoadjuvant chemotherapy defined as no residual invasive carcinoma within the breast (ductal carcinoma in situ [DCIS] permitted) and no evidence of metastatic disease within the lymph nodes, to be measured at surgery.

Key secondary outcome(s))
1. Disease-free survival, to be measured through follow-up
2. Overall survival, to be measured through follow-up
3. PathCR rate in breast alone, to be measured at surgery
4. Radiological response after 3 and after 6 cycles of chemotherapy
5. Rate of breast conservation, to be measured at surgery
6. Toxicities including in particular cardiac safety and surgical complications (wound healing, bleeding, and thrombosis), to be measured during treatment and follow-up

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Patients (aged 18 to 70 years [no age limit but must be fit enough to received chemotherapy], either sex) with histologically confirmed HER2-negative invasive breast cancer (either IHC 0/1 or IHC 2+ and fluorescence in situ hybridisation [FISH] negative)
2. T2 tumours and above (maximum tumour diameter greater than or equal to 20 mm from an ultrasound) and T4 tumours (including inflammatory breast cancer). For multi-focal tumours, the sum of each tumour's maximum diameter must be greater than or equal to 20 mm, and will be designated 'total tumour size'.
3. Any T stage with large axillary nodes (greater than 20 mm) and/or fixed axillary nodes (clinical N2)
4. Suitable for neoadjuvant chemotherapy in the opinion of the responsible clinician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

800

Key exclusion criteria
1. HER2 positive invasive cancer (IHC 3+ or FISH positive)
2. Uni-focal T0 and T1 tumours with no fixed axillary node or no node greater than or equal to 20 mm (multifocal tumours where the total tumour size [sum of maximum diameter of each lesion] is greater than or equal to 20 mm can be included - see above)
3. Patient not suitable for neoadjuvant chemotherapy in opinion of responsible clinician
4. Evidence of metastatic disease
5. Prior endocrine therapy
6. Prior history of breast cancer
7. Prior diagnosis of ischaemic heart disease, cerebrovascular disease, peripheral vascular disease, arterial or venous thrombo-embolic disease, cardiac failure, inflammatory bowel disease, gastro-duodenal ulcer, symptomatic diverticulitis, or bleeding diathesis
8. Uncontrolled hypertension

Date of first enrolment
01/04/2009

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC)

Funder Name
Roche (UK)

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Sanofi-Aventis (UK)

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?
Results article	results	01/06/2015		Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			26/10/2022	No	Yes