

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

Submission date 03/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

Dr Helena Earl

Contact details

Addenbrookes Hospital
Oncology Department, Box 193
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

EudraCT/CTIS number

2008-002322-11

IRAS number

ClinicalTrials.gov number

NCT01093235

Secondary identifying numbers

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Early breast cancer

Interventions

Arm A:

Docetaxel (D) 100 mg/m² intravenous (IV) x 3 cycles every 3 weeks (q3w) followed by 5-fluorouracil 500 mg/m² IV, epirubicin 100 mg/m² IV and cyclophosphamide 500 mg/m² (FEC) on day 1 x 3 cycles q3w

Arm B:

Docetaxel (D) 100 mg/m² 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 measure

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.

Secondary outcome measures

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

Overall study start date

01/03/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

800

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**

England

United Kingdom

Study participating centre

Addenbrookes Hospital

Cambridge

United Kingdom
CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type

Hospital/treatment centre

Website

http://www.cuh.org.uk/research/research_index.html

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.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Sanofi-Aventis (UK)

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