Objective:
A phase III, randomised trial to determine whether the addition to neo-adjuvant chemotherapy of an anti-angiogenic agent bevacizumab is more effective than standard chemotherapy alone in terms of short-term and long-term outcome in women presenting with HER2-negative early breast cancer. Associated translational science will use prospective molecular profiling and candidate gene analysis on paraffin-embedded and fresh tissue to define molecular predictors of response/ resistance to bevacizumab and chemotherapy. Quality of life and health economics sub-studies will collect data critical to any future health technology assessment of bevacizumab in this indication.

Trial Schema:

Core biopsy

Routine histopathology

Key Eligibility criteria
- Histologically confirmed HER2-negative invasive breast cancer
- T2 to T4 tumour and/or large axillary nodes (>20mm) and/or fixed axillary nodes (clinical N2)
- Suitable for neo-adjuvant chemotherapy

Randomisation with Stratification variables
- Age: ≤50 years; >50 years
- ER Status: negative; weakly positive, strongly positive
- 'Total Tumour size': ≤ 50mm; > 50mm (see section 5.2)
- Clinical involvement of axillary nodes: no; yes
- Inflammatory / Locally advanced disease (T4): no, yes

Arm A
D → FEC
Docetaxel [D]100mg/m2
IV d1 x 3 cycles q3w
followed by
5-Fluorouracil 500mg/m2
Epirubicin 100 mg/m2
Cyclophosphamide 500 mg/m2
[FEC] IV d1 x 3 cycles q3w.

Arm B
Bev + D → FEC
Bevacizumab [Bev]15mg/kg
Docetaxel [D]100mg/m2
IV d1 x 3 cycles q3w
followed by
Bevacizumab 15mg/kg
5-Fluorouracil 500mg/m2
Epirubicin 100 mg/m2
Cyclophosphamide 500 mg/m2
[Bev + FEC] IV d1 x 1 cycle q3w.
followed by
[FEC] IV d1 x 2 cycles q3w.

Surgery

Contact Details:

Chief Investigators
Dr Helena Earl
ARTEMIS Trial
Oncology Box 193 (R4)
Hills Road
Cambridge
CB2 0QQ
hme22@cam.ac.uk

Dr. Larry Hayward
Larry.hayward@luht.scot.nhs.uk

Trial Coordinators
Anne-Laure Vallier
ARTEMIS Trial
Cambridge Cancer Trials Centre
Box 279 (S4)
Addenbrookes Hospital
Hills Road
Cambridge
CB2 0QQ
Anne-laure.vallier@addenbrookes.nhs.uk

Louise Grybowicz
ARTEMIS Trial
Cambridge Cancer Trials Centre
Box 279 (S4)
Addenbrookes Hospital
Hills Road
Cambridge
CB2 0QQ
Louise.grybowicz@addenbrookes.nhs.uk

Clare Blenkinsop
ARTEMIS Trial
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road
Coventry
CV4 7AL
C.blenkinsop@warwick.ac.uk

Tel: 024 7615 1057