



## A Neoadjuvant Study of Chemotherapy Versus Endocrine Therapy in Postmenopausal Patients with Primary Breast Cancer

### BACKGROUND

**Neocent** is a randomised phase III trial comparing the effects of the aromatase inhibitor **Letrozole** versus the chemotherapy regimen **FEC<sub>100</sub>** in **post-menopausal women** with strongly **ER+** cancer.

### AI VERSUS CHEMOTHERAPY FOR DOWN-STAGING OF BREAST

**CANCER?** Many consider chemotherapy the gold standard of care for pre-operative down-staging of breast cancer, regardless of ER status. ER+ tumours respond less well to chemotherapy and the potential of chemotherapy for useful down-staging in strongly ER+ cancers is poorly documented. **Neocent is the first study to compare the response rates of AI versus chemotherapy in strongly ER+ tumours.**

### TRIAL DESIGN

The study is divided into 2 phases: '**Pilot**' phase and a '**Main**' Phase. The pilot study assesses the feasibility of patient recruitment and tissue collection for the main study. There are 3 sub-studies: 1. Tissue and Blood sampling (assessment of molecular predictors of treatment response, 2. MRI and 3. Quality of Life (QoL). The Feasibility Study aims to recruit 40 patients (20 per arm), the Main Study 716 patients (358 per arm)

#### ARM A

**FEC100 I.V. EVERY 3 WEEKS (6 CYCLES)**

#### ARM B

**LETROZOLE 2.5MG DAILY FOR 18-23 WKS**

### MAIN INCLUSION CRITERIA

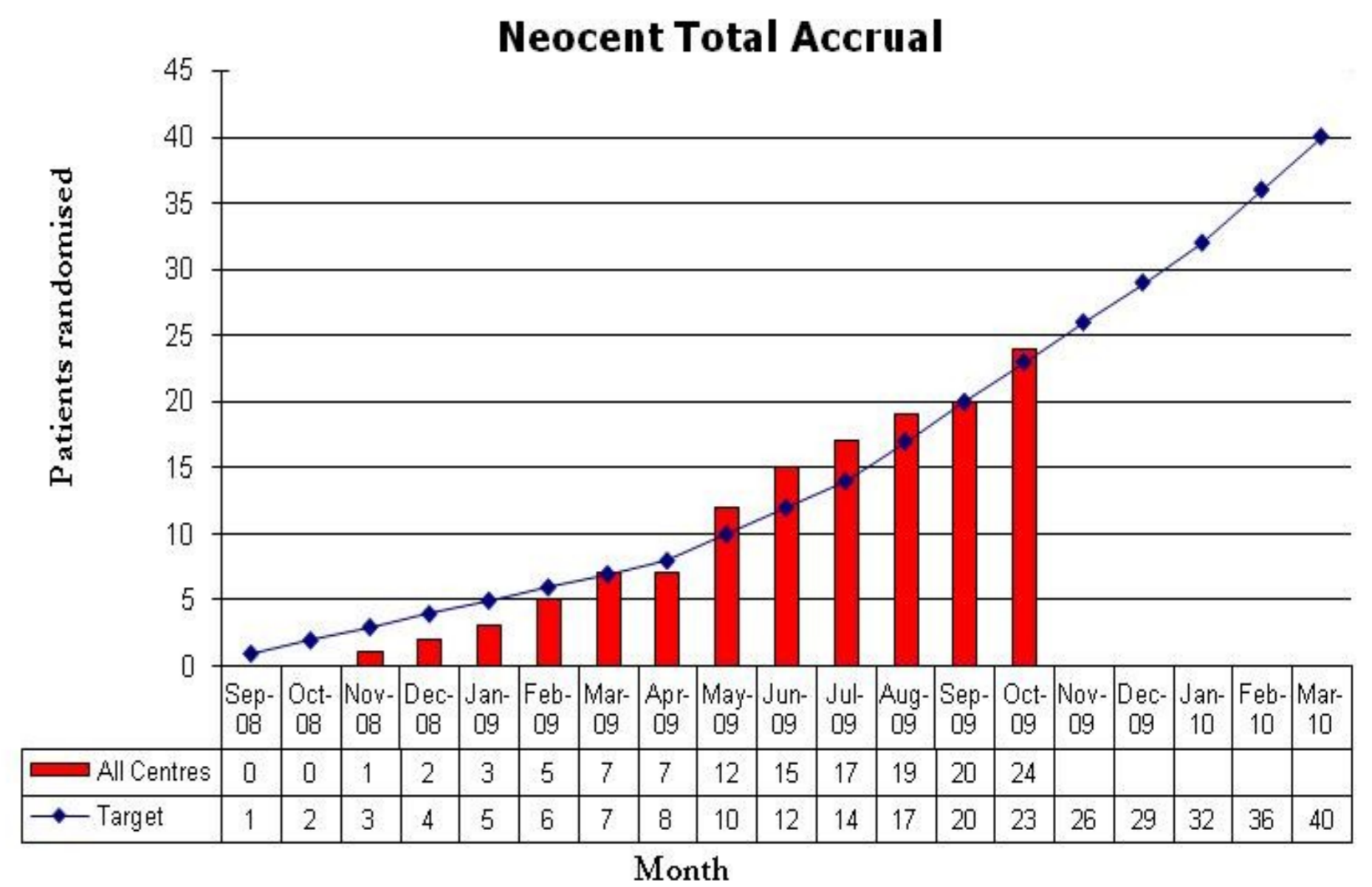
- PRIMARY INVASIVE BREAST CANCER SUITABLE FOR NEOADJUVANT TREATMENT
- T2 TUMOUR OR ABOVE (ULTRASOUND SIZE  $\geq 20$ MM) OR ANY T STAGE WITH NODAL DISEASE  $\geq 20$ MM DIAMETER ON ULTRASOUND ASSESSMENT
- ER+ TUMOUR: ALLRED 6/7/8, H-SCORE  $\geq 100$
- POSTMENOPAUSAL  $\leq 70$  YEARS OF AGE

### MAIN EXCLUSION CRITERIA

- INFLAMMATORY BREAST CANCER
- INOPERABLE DISEASE UNLIKELY TO BE RENDERED OPERABLE BY NEOADJUVANT TREATMENT
- ER POOR DISEASE
- BILATERAL INVASIVE BREAST CANCER

### TRIAL STATUS

**Neocent** is open at 8 centres (7UK, 1 South Korea) and has **RECRUITED 60% OF THE FEASIBILITY TARGET (24 PATIENTS):**



Recruitment is due to open shortly at another 4 centres, with a further 10 centres in set-up.

### UPDATES

### PLANNED PROTOCOL AMENDMENTS

- Inclusion of pre- and perimenopausal patients
- Starting dose FEC<sub>75</sub> at Investigator's discretion
- Switch to docetaxel after 3 cycles regardless of disease response at the Investigator's discretion.

### QUERIES?

If you have any queries or would like to know more about Neocent, please contact **DOMINIKA MISZTELA** (Trial Co-ordinator) [d.miszteła@imperial.ac.uk](mailto:d.miszteła@imperial.ac.uk)



## Breast Magnetic Resonance Imaging Sub-study

UNIVERSITY OF ABERDEEN, INSTITUTE OF MEDICAL SCIENCES, ABERDEEN BIOMEDICAL IMAGING CENTRE

### ASSESSMENT OF TUMOUR RESPONSE IN NEOADJUVANT THERAPY

Current assessment of tumour response to neoadjuvant chemotherapy is performed by clinical examination, ultrasonography and/or mammography, all of which have limited reliability. MRI has been found to be a useful method of measuring change in size and volume of tumours. It is considered by many as superior to other methods in assessing response.

Given the reliability and accuracy of this modality, **DYNAMIC CONTRAST ENHANCEMENT MRI** is used to **compare tumour responses to neoadjuvant endocrine therapy and chemotherapy.** MRI response is also one of the secondary endpoints of the study.

### MRI SCHEDULE

Tumours are assessed at **baseline, mid-treatment (optional)** and **pre-surgery.**

### RECORDING FEATURES AND ANALYSIS

For analysis, the index lesion is identified and measured in three planes using longest axis and perpendicular measurements. If software is available locally, then a volume measure is made using the dynamic frame with the highest tumour signal enhancement. The location of the index lesion is recorded, and any satellite lesions are identified and recorded in a similar fashion.

Reporting follows a simplified version of the BIRADS lexicon. The morphology (shape, margin etc.) and the enhancement features are recorded (pattern of enhancement, maximum signal enhancement rate, rate of signal enhancement in first 60 seconds, enhancement curve type). The region of interest (ROI) is placed within the highest enhancing area of the tumour. The ROI is kept small, ideally  $> 9$  and  $< 27$  pixels. A second ROI is used to cover the whole of the tumour in the central slice.

### MRI SUBSTUDY PARTICIPATING CENTRES

- CHARING CROSS HOSPITAL
  - GUY'S AND ST THOMAS HOSPITAL
  - WEST MIDDLESEX UNIVERSITY HOSPITAL
  - SOUTHAMPTON GENERAL HOSPITAL
  - BRISTOL HAEMATOLOGY AND ONCOLOGY CENTRE
- Substudy to open soon at
- ABERDEEN ROYAL INFIRMARY
  - DUNDEE NINEWELLS HOSPITAL

### MRI SUBSTUDY LEAD

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