

# First prospective Intergroup Translational Research Trial of the potential predictive value of p53 in patients with locally advanced /inflammatory or large operable breast cancer

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-see-if-p53-gene-damage-can-predict-how-well-different-chemotherapy-drugs-will-work-for-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Study information

### Scientific Title

First prospective Intergroup Translational Research Trial assessing the potential predictive value of p53 using a functional assay in yeast in patients with locally advanced/inflammatory or large operable breast cancer prospectively randomised to a taxane versus a non taxane regimen

### Acronym

p53 Study

### Study objectives

The study had two main objectives:

1. Test a treatment effect by comparing an anthracycline based regime (standard treatment) to a taxane plus anthracycline regimen ("new" treatment) separately in the normal and mutated p53 subgroups, p53 being assessed by a functional assay in yeast
2. Test an interaction effect between p53 status and the chemotherapy regimen (with or without taxanes)

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Multicentre Research Ethics Committee for Scotland, 11/12/2001, ref: MREC/01/0/22

### Study design

Multicentre randomised interventional treatment 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

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

### Interventions

1. Non-taxane arm: either FEC100 (epirubicin 100 mg/m<sup>2</sup> with 5-fluorouracil 500 mg/m<sup>2</sup> and cyclophosphamide 500 mg/m<sup>2</sup>) every 3 weeks for 6 cycles or Canadian FEC (oral cyclophosphamide on days 1-14 and epirubicin IV and fluorouracil IV on days 1 and 8) every 4 weeks for 6 cycles or tailored FEC (fluorouracil IV over 15 minutes, epirubicin IV over 1 hour, and cyclophosphamide IV over 1-2 hours on day 1; patients also receive filgrastim (G-CSF) subcutaneously on days 2-15 or until blood counts recover) x 6 (every 3 weeks for 6 cycles)
2. Taxane arm: 3 cycles Docetaxel (every 3 weeks for 3 cycles) followed by 3 cycles Epirubicin /Docetaxel (every 3 weeks for 3 cycles)

Follow up for both arms is till death  
Study entry: single randomisation only

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

5-FU, docetaxel, epirubicin

## **Primary outcome measure**

Progression free survival, calculated from date of randomisation to the first evidence of progression or recurrence or death, whichever occurs first

## **Secondary outcome measures**

1. Distant metastasis free survival, calculated from the date of randomisation to the first evidence of recurrent disease outside radiation field or death, whichever occurs first
2. Survival, calculated from date of randomisation to date of death
3. Clinical and pathological responses, assessed after 3rd cycle and at the end of neoadjuvant chemotherapy according to Response Evaluation Criteria in Solid Tumours (RECIST) criteria for tumour progression
4. Toxicity, measured according to Common Toxicity Criteria (CTC) scale version 2.0

## **Overall study start date**

25/04/2001

## **Completion date**

06/11/2006

# **Eligibility**

## **Key inclusion criteria**

1. Histologically confirmed breast cancer: Locally advanced or inflammatory disease:
  - 1.1. + T4a-d, any N, M0, or
  - 1.2. + Any T, N2 or N3, M0
  - 1.3. + Large T2 or T3 breast cancer requiring tumor shrinkage prior to breast conservation surgery
2. Frozen tumor sample available:
  - 2.1. One incisional biopsy, or

- 2.2. Two trucut biopsies from a 14G needle
3. No prior chemotherapy
4. No prior radiotherapy
5. Age: 70 and under
6. Female
7. Performance status: World Health Organization (WHO) 0 - 1
8. Neutrophil count greater than 1,500/mm<sup>3</sup>
9. Platelet count greater than 100,000/mm<sup>3</sup>
10. Bilirubin less than 1.2 mg/dL
11. Serum glutamic oxaloacetic transaminase (SGOT) less than 60 IU/L
12. Creatinine less than 1.35 mg/dL
13. Left ventricular ejection fraction (LVEF) normal by echocardiography or multiple gated acquisition scan (MUGA)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned sample size: 1850

**Key exclusion criteria**

1. No other malignancy within the past 5 years except basal cell or squamous cell skin cancer or carcinoma in situ of the cervix
2. No serious uncontrolled medical condition
3. No uncontrolled psychiatric or addictive disorders
4. Not pregnant or nursing
5. Fertile patients must use effective contraception

**Date of first enrolment**

25/04/2001

**Date of final enrolment**

06/11/2006

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Area 159C, 1st Floor**  
Edinburgh  
United Kingdom  
EH12 9EB

## **Sponsor information**

### **Organisation**

European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

### **Sponsor details**

Avenue Mounierlaan, 83/11  
Brussels  
Belgium  
1200

### **Sponsor type**

Research organisation

### **Website**

<http://www.eortc.be/>

### **ROR**

<https://ror.org/034wxcc35>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>				No	Yes