

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

Submission date 19/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/05/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/10/2018	Condition category Cancer	☐ Individual participant data
		☐ 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

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Additional identifiers

Protocol serial number

827

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

Primary study design

Interventional

Study design

Multicentre randomised interventional treatment trial

Study type(s)

Treatment

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/m² with 5-fluorouracil 500 mg/m² and cyclophosphamide 500 mg/m²) 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(s)

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

Key secondary outcome(s)

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

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/mm³
9. Platelet count greater than 100,000/mm³
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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

Scotland

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)

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

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?

[Plain English results](#)

No

Yes