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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

Contact name
Miss Kirsten Murray

Contact details
Area 159C, 1st Floor
Gyle Square
1 South Gyle Crescent
Edinburgh
United Kingdom
EH12 9EB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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/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 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 Evaulation 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^3
9. Platelet count greater than 100,000/mm^3
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?
Plain English results				No	Yes