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BASO II: a randomised trial for the management of small well-differentiated and special type carcinomas of the breast

Submission date	Recruitment status	[_] Prospectively registered
19/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2020	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00006030

Protocol serial number
BR9002

Study information

Scientific Title
BASO II: a randomised trial for the management of small well-differentiated and special type carcinomas of the breast

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
All patients receive wide local excision of primary tumour.

Following surgery patients are randomised to one of four treatment arms:
1. Arm A: Observation only.
2. Arm B: Tamoxifen, 20 mg daily for 5 years or until relapse.
3. Arm C: Radiotherapy only, the radiotherapy technique is at the discretion of the radiotherapist. Suggested fractionations are radiotherapy to the whole breast 40-50 Gy given in fifteen to twenty-five fractions followed by a boost to the tumour bed of 10-15 Gy in five to eight fractions. An iridium of caesium implant is an acceptable alternative.
4. Arm D: Radiotherapy as in Arm C plus tamoxifen, 20 mg daily for 5 years or until relapse.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
tamoxifen

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Aged <70 years
2. Unilateral invasive breast carcinoma grade I or of a special type:
a. Tubular
b. Tubular/cribriform
c. Cribriform
d. Papillary
e. Mucoid
f. Not lobular, medullary or other rarer special types of breast carcinoma
3. Tumour size <2 cm
4. No evidence of vascular invasion
5. The histological examination of at least one lymph node is required. There should be no evidence of metastases
6. No distant metastases
7. No other systemic disease
8. No previous invasive malignant disease, except basal cell carcinoma of the skin adequately treated or adequately treated in situ carcinoma of the cervix

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Patients with bilateral breast cancer, Paget's disease of the nipple, in situ carcinoma only or tumours which are essentially ductal carcinoma in situ but with microinvasion are to be excluded.

Date of first enrolment
25/03/1992

Date of final enrolment
31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Scottish Cancer Therapy Network (UK)

Funder(s)

Funder type
Research organisation

Funder Name
Scottish Therapy Network (UK)

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?
Results article	results	01/07/2013		Yes	No