ABS AT BASO

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Country: England

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Website: www.baso.org.uk/index/html/

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Title: BASO DCIS II TRIAL: Randomised trial testing observation (no radiotherapy) against radiotherapy in women with low-risk completely excised ER positive ductal carcinoma in situ (DCIS) of the breast on adjuvant endocrine therapy.

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Summary:

- Opened in March 2005
- Target accrual: 2000 patients

Multi-centre, prospective, randomised-controlled clinical trial, in which ER positive DCIS patients on tamoxifen are randomised to radiotherapy or no radiotherapy. The control arm delivers 50 Gy in 25 fractions or 40 Gy in 15 fractions to whole breast (no boost). The test arm will receive no radiotherapy.

Eligible postmenopausal patients may also be randomised into the IBIS II (DCIS) trial comparing tamoxifen with anastrozole as adjuvant endocrine treatment.

Objectives:

- Primary aims are to test the effects of withholding radiotherapy in terms of ipsilateral tumour relapse and quality of life.
- Secondary aims are to identify the minimum surgical margins required to minimise local recurrence rate and to identify molecular markers that predict for ipsilateral tumour recurrence.

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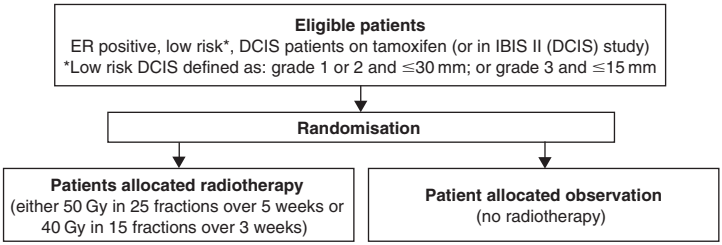
Scheme:



Update:

- Number of centres with ethics approval: 35 (8 centres have randomised patients to date).
- Total accrual: 15 patients.

Related Publications: None available

Topics:

- DCIS
- Radiotherapy
- Tamoxifen

Keywords: Low risk, ER positive, DCIS, radiotherapy, tamoxifen

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Title: Neoadjuvant trial of preoperative exemestane or letrozole ± celecoxib in the treatment of ER positive postmenopausal early breast cancer.

Acronym: NEO-EXCEL

Coordinator(s):

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Summary:

- Target accrual: 1000 subjects
- Planned start date: May 2006

Objective:

To determine whether the addition of a COX 2 inhibitor to an aromatase inhibitor results in greater objective clinical response, with acceptable toxicity, than an aromatase inhibitor alone and to determine whether exemestane provides greater objective clinical response than letrozole in the neoadjuvant setting:

- Primary endpoint: objective clinical response rate (CR, PR) during neoadjuvant treatment.
- Secondary endpoints: objective ultrasound-determined response (CR, PR) during neoadjuvant treatment; type of surgery; overall survival; progression-free survival.
- Biological profiling for prognostic and predictive indicators.

Proposed Trial Design:

- Phase III, prospective, multi-centre, four-arm, randomised clinical trial.
- Double-blind, placebo-controlled for assessment of the role of the COX 2 inhibitor, celecoxib, and open-label for the comparison of the aromatase inhibitors, exemestane and letrozole.
- Postoperative treatment will depend on operative pathology and be determined by local protocol but will require a minimum of one annual visit for 5 years.
- Patients who progress during the neoadjuvant phase will be withdrawn from the trial and be treated according to local protocol.

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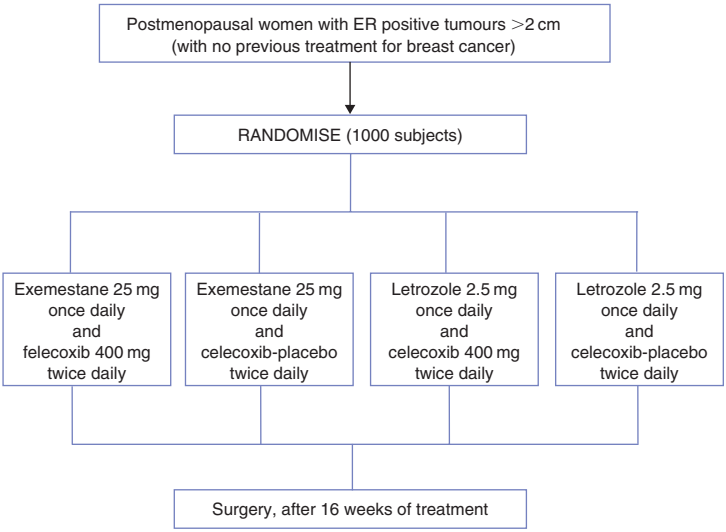

Update: None available

Related Publications: None available

Topics:

- Aromatase inhibitors
- Breast conservative treatment
- Celecoxib
- Hormonal therapy
- Hormone receptor positive breast cancer
- Postmenopausal patients

Keywords: Not provided

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