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Title: The NCRI Adjuvant Breast Cancer (ABC) trial.
ISRCTN31514446

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Summary:

- Opened in January 1993; closed in September 2000

Objective:

- To test whether adjuvant chemotherapy (CT) and/or ovarian suppression (OS) add to the benefits of tamoxifen in pre/perimenopausal women with early breast cancer.

Scheme:

Treatment plan for individual patients (not randomized)	Additional treatment options (randomized)	
	±OS	±CT
Tamoxifen	434	1747
Tamoxifen + CT	1710	–
Tamoxifen + OS	–	244
Total	2144	1991

*Patients in the double randomization (±CT, ±OS) count twice.

Substudies:

- Biological predictors of therapeutic response
- Quality of life

Update:

- Study closed; 3854 patients recruited (2144 pre/perimenopausal patients randomized to ±OS*, 637 pre/perimenopausal patients

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randomized to ±CT* and 1354 postmenopausal patients randomized to ±CT. Total of 1991 patients randomized to ±CT). Results were presented at ASCO 2004, and at several UK meetings. Manuscripts are in preparation. Recently received additional funding for translational research from BCC and CRUK for two studies – one to study p53 as a predictive response to CT and another to study markers for tamoxifen early *versus* late relapse.

Related Publications: None available

Topics:
- Tamoxifen
- Ovarian suppression
- Postmenopausal patients
- Premenopausal patients

Keywords: None available

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Title: The UK randomized trial of hormone replacement therapy (HRT) in women with a history of early stage breast cancer.
ISRCTN29941643

Coordinator(s): J. Marsden
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Summary:

- Opened in March 2002; closed to recruitment in February 2004
- Target accrual: 3000

Objectives:

- To assess the effect of HRT on disease-free survival and overall survival.
- The relief of menopausal symptoms and quality of life.
- Coronary heart disease, vascular events (i.e. thromboembolic, cerebrovascular) and osteoporotic fractures.

Scheme:

HRT arm:* If hysterectomised: unopposed oestrogen
If intact uterus: sequential combined therapy
continuous combined therapy

Choice and route of preparation will be determined by menopausal status and patient preference, where appropriate.

No-HRT arm – advice on: practical measures
clonidine
evening primrose oil
health foods
complementary medicine (e.g. reflexology, acupuncture, massage, meditation)

Low dose progesterones and phyto-oestrogen supplements are not recommended.

In both arms: preparation available for use for vaginal dryness.

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Update:	• 197 patients.
Related Publications:	None available
Topics:	• Hormone replacement therapy
Keywords:	Early breast cancer, HRT

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Title: NCRI Standardisation of Breast Radiotherapy (START) trial.
ISRCTN59368779

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Summary:

- Opened in January 1999; closed to recruitment in October 2002
- Target accrual: 2010 in Trial A (=670 per arm); 1840 in Trial B (=920 per arm).

Objective:

- To test the effects of radiotherapy schedules using fraction sizes larger than 2.0 Gy in terms of loco-regional tumour control, normal tissue responses, quality of life and economic consequences in women prescribed postoperative radiotherapy for early breast cancer.

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Scheme:

Trial A	Trial B
50 Gy/25 fractions (2.0 Gy)/5 weeks *versus* 40 Gy/15 fractions (2.67 Gy)/3 weeks *versus* 39 Gy/13 fractions (3.0 Gy)/5 weeks	50 Gy/25 fractions (2.0 Gy)/5 weeks *versus* 41.6 Gy/13 fractions (3.2 Gy)/weeks

Substudies:

Accrual (end December 2002)	Trial A	Trial B	Total
Quality of life study	1127 (*600*)	1078 (*400*)	2205
Photographic assessments	1311 (*1200*)	1093 (*800*)	2404
Blood sampling and family history questionnaires	1641	1208	2849

Italics = target sample size

Update:

- Trial B closed to recruitment in October 2001 with a total of 2215 patients.
- Trial A closed at the end of October 2002 with a total of 2236 patients.

Related Publications:

Brown J, Mills J, Haviland J, Bliss J, Yarnold J, on behalf of the START Trial Management Group. Productivity and health effects of radiotherapy in breast cancer patients. Poster presentation at the EORTC Economic Health Meeting, Brussels, September 2003 (Abstract published in *European Journal of Cancer Supplements* 2003; 1 (3): S10).

Mills J, Haviland J, Bliss J, Yarnold J, Hopwood P, on behalf of the START Trial Management Group. Quality of life (QL) assessment of anxiety and depression in the START trial for women with early breast cancer. Poster presentation at BOA, Manchester, 2003. *Clinical Oncology* 15 (6 Supplement 4): S32.

Mills J, Haviland J, Brown J, Hopwood P, Bliss J, Yarnold, J, on behalf of the START Trial Management Group. How soon do patients return to work after radiotherapy treatment for early stage breast cancer. Poster presentation at BOA, Edinburgh, 2004. *Clinical Oncology* 16 (6 Supplement 1): pS31.

Mills J, Brown J, Haviland J, Bliss J. How soon do patients return to paid and unpaid activities after radiotherapy treatment for early stage breast cancer in the START trial. Poster presentation at the British Psychosocial Oncology Meeting, Brighton, 2005.

Mills J, Moynihan C, Bliss J, Hopwood P. Quality of life in context: women's proffered comments on QL relate issues in early stage breast cancer. Poster presentation at NCRI Conference, Birmingham, 2005.

Mills J, Sumo G, Bliss J, Hopwood P. Changes in sexual functioning following treatment for early stage breast cancer in the START trial. Poster presentation at NCRI Conference, Birmingham, 2005.

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Sydenham M, Haviland J, Bliss J, Venables K, Yarnold J, on behalf of the START Trial Management Group. Evaluation of the effect of the START (Standardisation of Breast Radiotherapy) trial on radiotherapy practice in the UK. Poster presentation at BOA, Edinburgh, 2004. *Clin Oncol* 16 (6 Supplement 1): pS31.

Venables K, Winfield E, Aird E, Hoskin P, on behalf of the START Trial Management Group. Three-dimensional distribution of radiation within the breast. An intercomparison of departments participating in the START trial of breast radiotherapy fractionation. *Int J Radiat Oncol Biol Phys* 2003; 55 (1): 271–279.

Venables K, Miles E, Deighton A, Aird E, Hoskin P, on behalf of the START Trial Management Group. Irradiation of the heart during tangential breast treatment: a study within the START trial. *Br J Radiol* 2004; 77 (914): 137–142.

Venables K, Winfield E, Aird E, Hoskin P, on behalf of the START Trial Management Group. The use of *in vivo* thermoluminescent dosimeters in the quality assurance programme for the START breast fractionation trial. *Radiother Oncol* 2004; 71: 303–310.

Venables K, Miles EA, Hoskin PJ, Aird EG, on behalf of the START Trial Management Group. Verification films: a study of the daily and weekly reproducibility of breast patient set-up in the START trial. *Clin Oncol (R Coll Radiol)* 2005; 17 (5): 337–342.

Venables K, Miles EA, Aird EG, Hoskin PJ, on behalf of the START Trial Management Group. What is the optimum breast plan? – A study based on the START trial plans. *Br J Rad* 2006 (accepted January 2006).

Winfield E, Deighton A, Venables K, Hoskin P, Aird E, on behalf of the START Trial Management Group. Survey of tangential field planning and dose distribution in the UK: background to the introduction of the quality assurance programme for the START trial in early breast cancer. *Br J Radiol* 2003; 76: 254–259.

Yarnold J, Sydenham M, Haviland J, Mills J, Bliss J, on behalf of the START Trial Management Group. Update of the START (Standardisation of Breast Radiotherapy) trial. Poster presentation at UKRO Meeting, April 2003.

Topics:

- Radiotherapy
- Loco-regional relapse

Keywords: Radiotherapy, early breast cancer

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Title: TACT: A randomized trial of standard anthracycline-based chemotherapy (fluorouracil, epirubicin and cyclophosphamide (FEC) or epirubicin and CMF (Epi-CMF)) *versus* FEC followed by sequential docetaxel in women with early breast cancer.
ISRCTN 79718493

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Summary:
- Opened in February 2001; closed in July 2003
- Target accrual: 3340 – increased to 4000 in January 2003, final accrual: 4162

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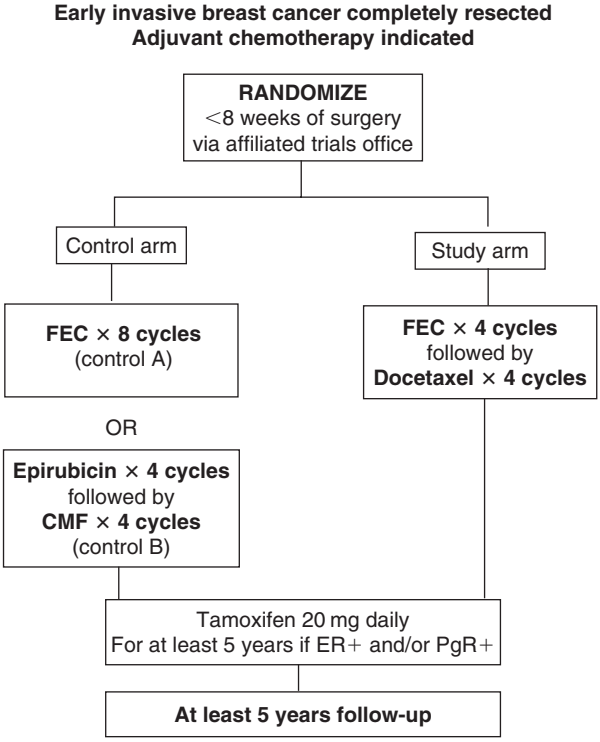
Scheme:



Update:

- In follow up: data collection has been streamlined to ensure release of outcome data as early as possible.
- Quality of life (QL) study: 829 patients participated in the QL study. An additional QL assessment at 5 years is planned in order to evaluate long-term survivorship issues.
- Biological studies: a collection of paraffin embedded tissue was completed, and tissue micro-arrays for over 3500 patients are in storage. A TRICC application for biological research is planned.
- A collection of blood samples from consenting TACT trial patients is still ongoing, with over 3000 blood samples collected. This is conducted in collaboration with breakthrough breast cancer.

Related Publications:

Bartlett JMS, Mallon EA, Forsyth A, *et al*. for the Trial Management Groups of TEAM and TACT. HER2 differentially affects invasive potential in ER −ve and ER +ve breast cancers. *JCO* 2005; 23: 16S 9557 (poster) ASCO, 2005.

https://doi.org/10.1017/S1470903106009266 Published online by Cambridge University Press

Barrett-Lee P, Bliss J, Ellis P, Hall E, Johnson L, Lawrence D, on behalf of the TACT Trial Management Group. Adjuvant taxanes for early breast cancer – clinical uncertainty exists. *Br J Cancer* 2001a; 85 (Suppl 1): 5.3 p20.

Barrett-Lee P, Bliss J, Ellis P, Hall E, Johnson L, Lawrence D, on behalf of the TACT Trial Management Group. Adjuvant taxanes for early breast cancer – clinical uncertainty exists. British Breast Group, July 6–7 2001b, Glasgow.

Hall E, Johnson L, Ellis P, Barrett-Lee P, Bliss JM, on behalf of the TACT Trials Management Group. How complete follow up (FU) datasets within the TACT trial could bring forward the release of outcome data. NCRI Cancer Conference, 2005 (poster).

Hopwood P, Ellis P, Barrett-Lee P, *et al*. on behalf of the TACT Trial Management Group. Impact on quality of life (QL) during chemotherapy (CT) of FEC-T compared to FEC or E-CMF: results from the UK NCRI Taxotere as Adjuvant Chemotherapy Trial (TACT). *JCO* 2005; 23: 16S 661 (poster) ASCO, 2005.

Hopwood P, Ellis P, Barrett-Lee P, *et al*. on behalf of the TACT Trial Management Group. Patients' views of distress and interference with daily activities due to side effects from chemotherapy for early breast cancer: the TACT (Taxotere as Adjuvant ChemoTherapy) trial experience. *EBCC* 2006a (poster).

Hopwood P, Ellis P, Barrett-Lee P, *et al.*, on behalf of the TACT Trial Management Group. A comparison of clinician and patient symptom reporting during chemotherapy for adjuvant breast cancer: the TACT (Taxotere as Adjuvant ChemoTherapy) trial experience. *EBCC* 2006b (poster).

Johnson L, Bliss J, Ellis P, Barrett-Lee P, Johnston S, Yarnold J, for the Trial Management Groups and Trial Steering Committees for START and TACT. UK patients are willing to donate biological material for substudies in clinical trials. *Eur J Cancer* 2003; 1 (5): 416 (poster).

Johnson L, Bliss J, Johnston S, Ellis P, Yarnold J, for the Trial Management Groups and Trial Steering Committees for START and TACT. Patients are willing to donate biological material for substudies in clinical trials. *Clin Oncol* 2003; 15 (6): p4.1 (poster).

Johnson L, Bliss J, Johnston S, Yarnold J, for the Trial Management Groups and Trial Steering Committees for START and TACT. Biological substudies in clinical trials – UK patients are willing to donate biological material. *Eur J Cancer* 2003; Suppl 1 (4): O83 (oral presentation).

Johnson L, Bliss JM, Ellis P, Barrett-Lee P, Johnston S, on behalf of the TACT Trial Management Group. Blood samples for biological research – acceptance rate within the TACT trial. NCRI Cancer Conference, 2005 (poster).

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Johnson L, Barrett-Lee P, Bliss J, on behalf of the TACT Trial Management Group. How do patients want to learn of results of clinical trials? – results of a survey of 1431 breast cancer patients taking part in the TACT trial. *EBCC* 2006 (poster).

Johnston SRD, Johnson L, Dowsett M, *et al*. on behalf of the TACT Trial Management Group – HER-2 status in primary breast cancer patients treated in the UK TACT trial – relationship with tumour size, grade, nodal involvement and ER status. *Breast Cancer Research and Treatment 26th San Antonio Breast Cancer Symposium* 2003; 82 (Suppl 1) (poster).

Topics: None available

Keywords: None available

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Title: SoFEA: Study of Faslodex with or without concomitant Arimidex *versus* Exemestane following progression on non-steroidal Aromatase inhibitors.
ISRCTN: 44195747

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Summary:

- Open to recruitment

Primary Objectives:

- To compare the progression-free survival of patients treated with Faslodex plus concomitant Arimidex *versus* Faslodex alone.
- To compare the progression-free survival of patients treated with Faslodex alone *versus* those treated with the current standard, Exemestane.

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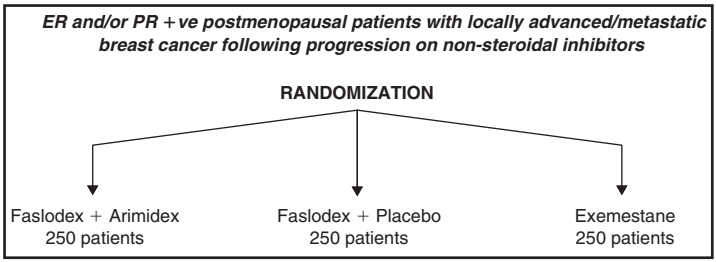
Exploratory:

- To establish in accessible tumour biopsies from as many patients as possible relapsing on NSAIs, and in circulating tumour cells before and during treatment: tumour ER expression and activation status (i.e. phosphorylation status); tumour EGFR/HER2 expression and activation of the MAPK/ERK/IGFR/AKT signalling pathways.

Scheme:



Update:

- Study opened to recruitment in March 2004. To end of January 2006, 110 patients randomized. Target accrual is 750 patients. Currently there are 85 open sites, 39 of which have randomized at least one patient.

Related Publications: None available

Topics:

- Locally advanced breast cancer
- Metastatic breast cancer
- Postmenopausal patients
- Hormone receptor positive breast cancer
- Hormonal therapy
- Aromatase inhibitors
- Blood markers
- Multiple drug resistance
- Predictive markers

Keywords: None available

https://doi.org/10.1017/S1470903106009266 Published online by Cambridge University Press

Title: TACT2: Trial of accelerated adjuvant chemotherapy with Capecitabine in early breast cancer.
ISRCTN68068041

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Summary:

- Opened in December 2005
- Target accrual: 4400

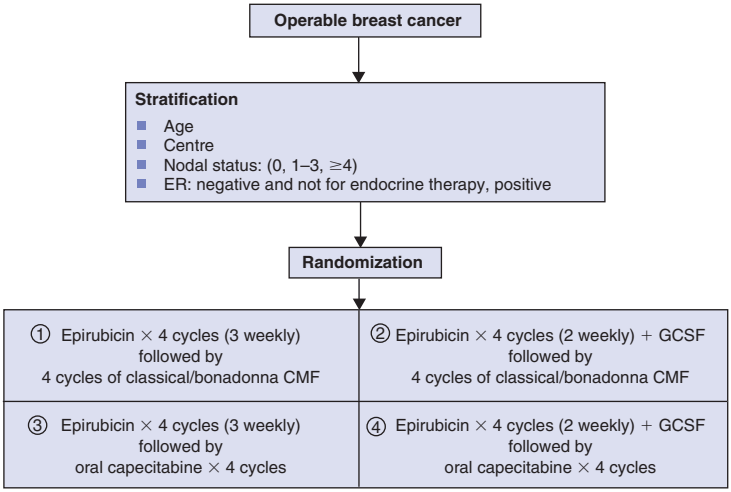
Objective:

- To assess whether accelerating the administration of adjuvant epirubicin, when given before CMF or Capecitabine, will improve its efficacy, and to evaluate whether the use of oral Capecitabine instead of CMF (after epirubicin) will be at least as effective as CMF and less toxic.

Substudies:

- Quality of life
- Biological
- Health economics

Scheme:



Update:

- 55 patients recruited to end of February 2006.

Related Publications: None available

Topics: None available

Keywords: Adjuvant chemotherapy

https://doi.org/10.1017/S1470903106009266 Published online by Cambridge University Press

Title: FAST trial: Prospective randomized clinical trial testing 5.7 Gy and 6.0 Gy fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control.

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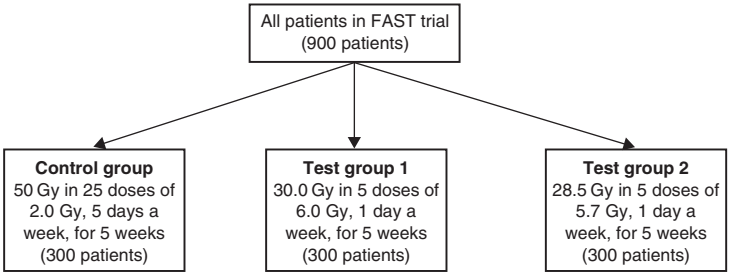
Summary:

- The trial opened in October 2004
- Target accrual: 900 patients (300 per trial arm)

Objective:

- To test 5 fractions of 5.7 and 6.0 Gy against 25 fractions of 2.0 Gy in terms of late normal tissue effects and tumour control in women prescribed whole breast radiotherapy (no boost) after local excision of early breast cancer.

Scheme:



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Update:
- 413 patients have been recruited into the trial by 1 March 2006 from a total of 21 centres.

Related Publications: None available

Topics:
- Radiotherapy
- Breast conservative treatment

Keywords: Hypofractionation, radiotherapy, breast cancer

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Title: IMPORT low trial.

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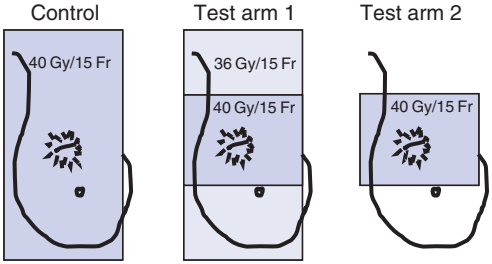
Summary:

- Target accrual: 1935 patients

Objective:

- To test partial breast radiotherapy delivered using intensity modulated techniques following complete local tumour excision of low risk early breast cancer.

Scheme:



Update:

- Recruitment opened in July 2006.

Related Publications: None available

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Topics:
- Radiotherapy
- Loco-regional relapse
- Breast conservative treatment

Keywords: Partial breast radiotherapy, intensity modulated radiotherapy, low risk, breast cancer

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Title: IMPORT high trial.

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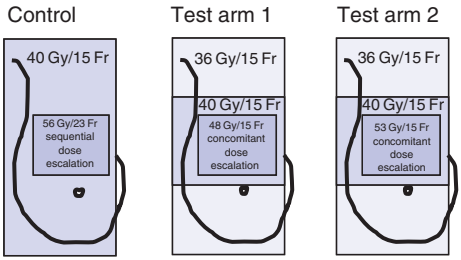
Summary:

- Target accrual: 840 patients

Objective:

- To test dose escalated intensity modulated radiotherapy after conservation surgery for early breast cancer in women with higher than average local recurrence risk.

Scheme:



Update:

- Recruitment opened in July 2006.

https://doi.org/10.1017/S1470903106009266 Published online by Cambridge University Press

Related Publications:	None available
Topics:	• Radiotherapy • Loco-regional relapse • Breast conservative treatment
Keywords:	Dose escalation, intensity modulated radiotherapy, high risk, breast cancer

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Title: Adjuvant chemotherapy in older women (ACTION).

Coordinator(s): Professor R. Leonard
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Summary:

- Due to open in Summer 2006
- Target accrual: 1000

Objectives:

- To test the benefit of adjuvant chemotherapy (either AC or EC) in terms of disease-free survival in older women with high risk, ER negative/ER weakly positive breast cancer.
- To evaluate accelerated therapy with GCSF in terms of toxicity in this patient group.
- To evaluate the acceptability and tolerability of both chemotherapy regimens in this group of patients.

Substudies:

- Quality of life
- Biological

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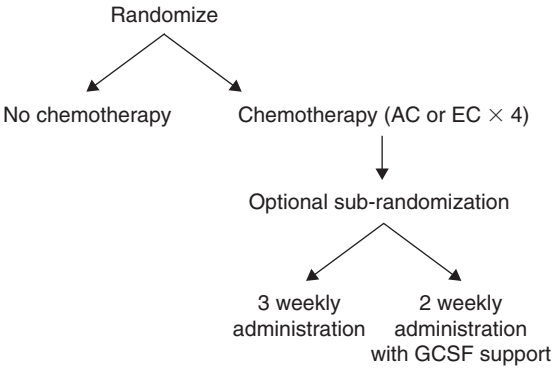
Scheme:



Update:

- Recruitment opened in Summer 2006.

Related Publications: None available

Topics: None available

Keywords: Adjuvant, older women

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