



Fondation du Centre
Pluridisciplinaire d'Oncologie

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ZOOM SOLE

Indication	Sein adjuvant (post-ménopausée/ récepteurs hormonaux +)
Title	A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone receptor positive, node positive early stage breast cancer
Protocol ID	SOLE (BIG 1-07/ IBCSG 35-07)
Phase	Phase III
Sponsor	IBCSG (International Breast Cancer Study Group)
Local Principal Investigator	Dr K. Zaman
Primary Objective	This trial will compare continuous letrozole for five years with intermittent letrozole over a five year period for postmenopausal women who are disease-free following 4-6 years of prior adjuvant endocrine therapy with SERM(s) and/or AI(s) for endocrine-responsive node-positive operable breast cancer.
Inclusion/exclusion criteria	<p>Inclusion/exclusion Criteria include the following :</p> <p>Patient characteristics</p> <ul style="list-style-type: none"> ○ Patients must be postmenopausal using any one of the following criteria. Because letrozole is not effective in pre- or perimenopausal patients, and may stimulate ovarian function, definitive confirmation of postmenopausal status is required. ○ Patients must be accessible for follow-up. <p>Disease characteristics</p> <ul style="list-style-type: none"> ○ At diagnosis, patients must have had operable, non-inflammatory breast cancer. ○ Patients must be clinically disease-free at randomization. (Note: It is recommended but not required that disease-free status be verified by abdominal ultrasound, chest xray, and bone scan (if symptomatic). A mammogram within one year prior to randomization is recommended. ○ Patients must have had steroid hormone receptor positive tumors (ER and/or PgR), determined by immunohistochemistry, after primary surgery and before commencement of prior endocrine therapy. ○ Following primary surgery, eligible patients must have had evidence of lymph node involvement either in the axillary or internal mammary nodes, but not supraclavicular nodes. ○ There must have been no evidence of recurrent disease or distant metastatic disease at any time prior to randomization.

- Not eligible: Patients who have had bilateral breast cancer.

Prior surgery and radiotherapy

- Patients must have had proper local treatment including surgery with or without radiotherapy for primary breast cancer with no known clinical residual loco-regional disease.

Prior/concurrent disease and conditions

- Patients must have clinically adequate hepatic function.
- Not eligible: Patients who have had a bone fracture due to osteoporosis at any time during the 4-6 years of prior endocrine SERM/AI therapy.
- Not Eligible: Patients who have had any previous or concomitant malignancy EXCEPT adequately treated: basal or squamous cell carcinoma of the skin, in situ carcinoma of the cervix or bladder, contra- or ipsilateral in situ breast carcinoma.
- Not eligible: Patients who have had any other non-malignant systemic diseases (cardiovascular, renal, lung, etc.) that would prevent prolonged follow-up.
- Not eligible: Patients with psychiatric, addictive, or any disorder which compromises compliance with protocol requirements.

Prior treatment

- Patients must have completed 4 to 6 years of prior adjuvant endocrine therapy with SERM(s), aromatase inhibitor(s), or a sequential combination of both. When calculating 4-6 years, neoadjuvant endocrine therapy should not be included.
- Patients must have stopped prior endocrine SERM/AI therapy, and must be randomized within 12 months (1 year) of the last dose of prior endocrine SERM/AI therapy.
- Patients may have received any type of prior adjuvant therapy, including but not limited to neoadjuvant chemotherapy, neoadjuvant endocrine therapy, adjuvant chemotherapy, trastuzumab, ovarian ablation, GnRH analogues, lapatinib.

Concurrent treatment

- Patients must have stopped hormone replacement therapy (HRT), bisphosphonates (except for treatment of bone loss), or any investigational agent at randomization. (Note: These agents are also not permitted during trial treatment.)

Protocol requirements before randomization

- Pathology material from the primary tumor must be available for submission for central review as part of the quality control measures for this protocol.
- Written Informed Consent (IC) must be signed and dated by the patient and the investigator prior to randomization.
- Written consent to pathology material submission, indicating the patient has been informed of and agrees to tissue material use, transfer and handling, must be signed and dated by the patient and the investigator prior to randomization.

