



Fondation du Centre
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

ZOOM SUPREMO (BIG 2-04)

Indication	Sein Radiothérapie ADJUVANTE
Title	SUPREMO , an MRC phase III randomised trial to assess the role of adjuvant chest wall irradiation in 'intermediate risk' operable breast cancer following mastectomy. (S elective Use of P ostoperative R adiotherapy A ft E r M astect O my)
Protocol ID	SUPREMO (BIG 2-04)
Phase	Phase III
Sponsor	UK Medical Research Council, Scottish Cancer Trials Breast Group in association with the Breast International Group.
Local Principal Investigator	Dr W. Jeanneret Sozzi
Goal	To determine the effect of Ipsilateral chest wall irradiation following mastectomy and axillary clearance for women with operable breast cancer at 'intermediate risk' of loco-regional recurrence on overall survival.
Inclusion/exclusion criteria	<p>Inclusion criteria include the following:</p> <ul style="list-style-type: none"> ○ pT1, pN1, M0 unilateral histologically confirmed invasive breast cancer. ○ pT2, pN1, M0 unilateral histologically confirmed invasive breast cancer. ○ pT2, pN0 unilateral histologically confirmed invasive breast cancer if grade III histology and/or lymphovascular invasion. ○ Multifocal breast cancer if largest discrete tumour at least 2cm if N0 and grade III histology and/or lymphovascular invasion. ○ If the tumour area comprises multiple small adjacent foci of invasive carcinoma then overall maximum dimension taken. This must be greater than 2cm if N0 and grade III histology and/or lymphovascular invasion. ○ Fit for adjuvant chemotherapy (if indicated), adjuvant endocrine therapy (if indicated) and postoperative irradiation. ○ Undergone total mastectomy (with minimum of 1mm clear margin) and axillary staging procedure. ○ If axillary node positive (1-3 positive nodes [including micrometastases >0.2mm-≤2mm]) then an axillary node clearance (minimum of 10 nodes removed) should have been

	<p>performed. Isolated tumour cells do not count as micrometastases.</p> <ul style="list-style-type: none">○ Axillary node negative status can be determined on the basis of either axillary clearance or axillary node sampling or sentinel node biopsy.○ Written, informed consent. <p>NB Patients undergoing immediate breast reconstruction are eligible for inclusion.</p> <p>Exclusion criteria include the following:</p> <ul style="list-style-type: none">○ Any pT0, pN0-1, or pT1, pN0 or pT3, pN0-1 or pT4○ Patients who have 4 or more pathologically involved axillary nodes○ Patients who have undergone neoadjuvant systemic therapy○ Previous or concurrent malignancy other than non melanomatous skin cancer and carcinoma in situ of the cervix○ Male○ Pregnancy○ Bilateral breast cancer○ Known BRCA1 and BRCA2 carriers○ Not fit for surgery, radiotherapy or adjuvant systemic therapy○ Internal mammary nodes positive on sentinel node scintigraphy○ Unable or unwilling to give informed consent
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