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Successful trans-Atlantic collaboration in a randomised controlled trial in osteosarcoma: EURAMOS1 (ISRCTN67613327; a trial conducted as part of ECT-EUROCORES) – a potential model for collaboration in rare diseases

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Aim:

Randomised controlled trials are needed to assess new approaches to treatment. In rare cancers, like osteosarcoma, RCT can only be performed with international collaboration.

Methods:

Four multinational groups from Europe & North America (COG, COSS, EOI, SSG) collaborate in EURAMOS1 within the European Science Foundation's ECT-EUROCORES (www.esf.org) scheme, led from MRC Clinical Trials Unit (London, UK). All patients receive MAP chemotherapy (methotrexate, adriamycin, cisplatin) prior to surgery & are risk-stratified after surgery: "good responders" are randomized to continued MAP or MAP followed by maintenance pegylated interferon; "poor responders" are randomized to either continued MAP or MAPIE (MAP, ifosfamide, etoposide). The outcome measures are event-free survival, overall survival, toxicity and quality of life. 1400 registered patients are planned over 4 years. An efficient infrastructure has been set up to ensure the successful running of the trial. (www.euramos.org)

Results:

A successful collaboration has been initiated. To 31-Oct-2007, accrual was on target, with 752 patients registered from over 200 institutions in 13 countries since summer 2005, including 96 UK patients (13% total). Four fifths are under 18-years old. International awareness of the trial is ever-increasing; further countries can apply to join the trial.

Conclusions:

International clinical trials in rare diseases are practicable providing there is appropriate funding, sponsorship, planning & infrastructure. EURAMOS1 may serve as a model for successful multi-national academic clinical trials in times of increasing economic & regulatory pressure. It has the quickest accrual rate of any osteosarcoma trial ever and is now the largest osteosarcoma study ever conducted.