Scientific Report

ECT-Dissemination Activity

Oral presentation at the 24th Annual Meeting of the European Musculo-Skeletal Oncology Society (EMSOS), Ghent, Belgium. May 18-20, 2011

Summary

The European Musculo-Skeletal Oncology Society EMSOS is an international, interdisciplinary association with a constituency of orthopaedic surgeons, medical and paediatric oncologists, pathologists, radiologists, radiotherapists and others with an interest in bone and soft tissue sarcomas. Many EMSOS-members are from institutions which actively participate in the ECT-EURAMOS EUROCORES, others come from other groups which also perform clinical trials in bone tumours, usually on a national basis.

The dissemination activity, an oral presentation at the meeting, focused on (de-)centralization of recruitment observed within the European and American Osteosarcoma Study EURAMOS-

Description of the scientific content of and discussion at the event

The 2011 meeting of the European Musculo-Skeletal Oncology Society EMSOS on May 18.20, 2011, included sessions covering the different fields of expertise in sarcoma management. Almost each session started with a short invited lecture. The conference was again preceded by a training day for junior physicians and was accompanied by a meeting of nurses and allied health professionals. Scientific sessions of the main meeting again covered a wide spectrum of bone and soft-tissue oncology and were of interest to specialists of multiple fields, including medical and pediatric oncology, orthopaedic surgery, radiology, radiotherapy, pathology, and others. Attracted by the training day, many junior doctors also attended the meeting. In addition to European delegates, the meeting was also attended by doctors from other continents, proving that the format was attractive. All abstracts were subject to plenary discussions.

Presentation made by the applicant at the event

The ECT-EURAMOS presentation was held to an audience of approx. 200 delegates. It was included in the session “Study Protocols” on Thursday, May 19. (see attached conference program). The content of the presentation was as summarized in the abstract below:

Osteosarcoma treatment in Europe and elsewhere is far from being centralized: Lessons from EURAMOS-1 (NCT00134030)

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Introduction: Investigator initiated clinical trials in rare cancers require multi-institutional collaboration, yet the challenges associated with such trials increase with increasing numbers of participating institutions. Using data from the EURAMOS-1 trial, recruiting since 04/05 and expected to complete recruitment mid 2011, we used osteosarcoma as an example to describe the institutional context from which patients with rare cancers can currently be recruited.

Material and Methods: Analysis of the EURAMOS Accrual Report January 2011 for institutional variables.

Results: 2,106 patients from 419 institutions were registered, including 1,023 patients from 240 institutions in 13 European countries (A 22, BE 42, CH 38, CZ 7, DK 25, FIN 3, D 408, H 24, IRE 2, NL 95, N 39, SE 44, UK 274). The degree of centralization varied considerably between European countries, only 4/13 averaged a total of >10 patients/center. Worldwide, only 3/419 participating institutions recruited >5 patients per year. The top ten recruiters (USA 4, D 3, N/NL/UK 1 each) accounted for 15.5% of all patients (327), the remaining 409 (97.6%) for 84.5% (1,779).

Conclusions: Despite various attempts towards increased centralization, osteosarcoma patients in Europe and elsewhere are still dispersed across multiple institutions. This considerable fragmentation of care needs to be taken into account when planning, initiating, running, and particularly when regulating large scale clinical trials in rare cancers. Otherwise, successful studies are unlikely to happen.

Supported by the European Science Foundation (ESF) under the EUROCORES Program European Clinical Trials (ECT), through contract No. ERASCT-2003-980409 of the European Commission, DG Research, FP6

Interestingly, circumstances well beyond the influence of trialists seem to affect centralization of patients with rare diseases much more than factors which they can influence. As an example, the 41 centers belonging to one of the six European monarchies participating in

ECT-EURAMOS recruited 11.0 +/- 14.1 patients per center, compared to only 6.0 +/- 5.9 in the 287 centers in the remaining 11 participating countries worldwide. We concluded that, unless major political changes occur, considerable fragmentation of care needs to be taken into account when planning, initiating, running, and regulating large scale clinical trials in rare cancers.

Assessment of the results and impact of the event on the EUROCORES programme

The ECT-EUROCORES program is nearing conclusion. We demonstrated that this pan-European effort contributed substantially to the successful implementation and running of by far the largest osteosarcoma study ever performed. The results of the presented analysis also clearly demonstrate the dire need for international funding programs for large-scale clinical trials in rare cancers, as such trials are only feasible if performed in multiple sites and across many countries. Due to a remarkable degree of de-centralised care, selection of only few centres in few countries is not feasible. Rather, the fragmentation of care needs to be taken account of.

Other comments / annexes

- Final Programme of the Meeting
- ppt of the ECT-EURAMOS presentation
- registration confirmation

Stuttgart, July 29, 2011 Prof. Dr. Stefan Bielack