Euro-E.W.I.N.G. 99 Trial Synopsis

Description, Study Objectives, Endpoints and Overview

Description, study objectives and endpoints

This is a randomised, prospective, multi-centre, international study, linking several co-operative groups, to improve outcome in patients with Ewing tumour. The treatment is stratified according to prognostic factors as determined by previous studies.

Objectives are:

1. To compare, in a randomised trial, VAI consolidation chemotherapy with VAC consolidation chemotherapy in patients with non-metastatic Ewing tumour and good histological response to standard induction VIDE chemotherapy, or in patients with localised Ewing tumour < 200 ml in volume who receive radiotherapy as primary local treatment following standard induction VIDE chemotherapy (Randomisation R1).
2. To compare, in a randomised trial, VAI consolidation chemotherapy with high-dose therapy (Busulfan-Melphalan) and PBPC rescue, A: in patients with non-metastatic Ewing tumour and poor histological response to standard induction VIDE chemotherapy, B: in patients with localised Ewing tumour ≥ 200 ml in volume who receive radiotherapy for local control following standard induction VIDE chemotherapy and Busulphan-Melphalan where applicable (Randomisation R2loc).
3. To compare, in a randomised trial, VAI consolidation chemotherapy and whole lung irradiation with high-dose therapy (Busulfan-Melphalan) and PBPC rescue, in patients with pulmonary or pleural metastases at diagnosis (Randomisation R2pulm).
4. To recommend and develop therapy for patients with metastases at sites other than pulmonary/pleura, - i.e., bone and/or bone marrow (R3).
5. To study the prognostic significance of EWS-Fli1 transcript type.
6. To study the frequency and prognostic value of minimal disease in bone marrow and PBPC harvest, as determined by the presence or absence of EWS-Fli1 transcript.

Primary endpoints are event-free survival (EFS) and overall survival (OAS).

Secondary endpoints are
a) feasibility, toxicity and response to VIDE induction therapy
b) feasibility, and toxicity of randomised consolidation regimens
c) EFS and OAS by prognostic group analysis

Study Overview