

IELSG

INTERNATIONAL EXTRANODAL LYMPHOMA STUDY GROUP

TRIALS COORDINATION CENTRE: ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND

OSPEDALE SAN GIOVANNI - CH-6500 BELLINZONA - SWITZERLAND

E. ZUCCA, A. CONCONI, F. CAVALLI / C. MORININI, M. TROVESTI

PHONE ++41 91 811 90 40 - 811 91 11 - FAX ++41 91 811 91 82 - E-MAIL ielsg@ticino.com - www.ielsg.org

NEWSLETTER 17

APRIL 2004

Highlights of the 7th IELSG annual meeting held in Barcelona

Dear all,

The recent meeting held in Barcelona gave us, as usual, the opportunity to review the ongoing studies, to compare our experiences and to discuss some new proposals. Here's the minutes of the meeting.

The ongoing studies

IELSG 4: Chemotherapy vs chemotherapy plus irradiation in diffuse large-cell gastric lymphoma.

- The patient enrolment will be closed on June 30th 2004. A manuscript will be prepared

IELSG 10: A phase II study of CHOP, with intrathecal methotrexate followed by radiotherapy, in patients with primary testicular non-Hodgkin's lymphoma.

- The participation of some US centers has been announced

IELSG 11: Retrospective evaluation of localized primary cutaneous B-cell lymphomas

- The patient registration has been completed, the final analysis has been proposed, a paper is in preparation

IELSG 17: Multi-institutional retrospective analysis of intravascular lymphomatosis

- Final analysis has been showed, in the last few days a paper from this study has been accepted for publication on Annals of Oncology. Additional manuscripts are in preparation

IELSG 18: Retrospective international survey on primary effusion lymphomas

- A preliminary analysis has been presented, a forthcoming pathological review has been announced

IELSG 14: Retrospective evaluation of primary bone lymphoma

- The retrospective study is closed, a final analysis will be performed in the next few months.

A IELSG working party on bone lymphoma will be constituted. The current Australasian prospective study called TROG 99.04 would become an IELSG trial. Information concerning this prospective study will follow soon

IELSG 15: Retrospective evaluation of primary breast lymphoma

- The European series of patients underwent pathological review in Milan; before the final analysis a pathological review of the Australasian cases should be attempted

IELSG 19: Multicenter randomized trial of chlorambucil versus chlorambucil plus rituximab in extranodal marginal zone B-cell lymphoma of mucosa associated lymphoid tissue (MALT lymphoma)

- Great satisfaction has been expressed about the high accrual rate observed during the first year

IELSG 20: Randomized phase II trial on primary chemotherapy with high-dose methotrexate, alone or associated with high-dose cytarabine, followed by response- and age-tailored radiotherapy for immunocompetent patients with newly diagnosed primary central nervous system lymphoma.

- During the meeting ethical committee approval procedures were still ongoing, the first patients have been enrolled in March 2004

IELSG 23: Retrospective evaluation of primary head and neck lymphoma

- Preliminary data have been presented, the data registration and the collection of pathological material for biological studies is ongoing

Forthcoming studies and new proposals

IELSG 21: Salvage therapy with idarubicin in immunocompetent patients with relapsed or refractory primary central nervous system lymphomas

IELSG 22: Gastric irradiation for MALT lymphoma: a retrospective study

Trial of cytotoxic T-cell therapy for post transplant lymphoproliferative disease. D. Crawford, Edinburgh UK

- The IELSG has already contributed to circulate the study protocol in order to verify the feasibility of the trial in a multicenter international setting

Phase II study of on Primary *Chlamydia psittaci* eradicating antibiotic therapy for immunocompetent patients with newly diagnosed or relapsed ocular adnexal lymphoma

- Based on biological data and preliminary clinical results suggesting a pathogenetic link between *Chlamydia psittaci* and MALT lymphoma of the ocular adnexa, a phase II study of antibiotic therapy in orbital MALT lymphomas has been proposed, a protocol will be prepared soon

Moreover...

International PCNSL Collaborative Group (IPCG) Workshop

Barcelona, March 3, 2004

Current therapeutic knowledge in primary CNS lymphomas results mostly from non-randomized phase-II trials. It is critical that the results of these trials be reported in a manner that allows for a reasonable comparison. During the last IELSG Annual Meeting, L. Abrey (MSKCC, New York), T. Batchelor (MGH, Boston), A. J. M. Ferreri (HSR, Milan), E. Jacobsen (Denmark), and E. Zucca (IOSI, Bellinzona) analyzed previously reported prospective trials performed by IPCG members and other correlated fonts to develop uniform criteria for the conduct and reporting of clinical trials in patients with newly diagnosed PCNSL. Several aspects regarding baseline labs, staging, neurocognitive evaluation, definition of measurable disease, role of RECIST, Mac Donald's and Cheson's criteria, disease parameters useful in response definition, and minimum standard endpoints to report have been discussed. With the participation of a larger number of IPCG members, the debate on these relevant methodological issues will continue during the next ASCO Annual Meeting (New Orleans, Louisiana, June

5-8). Ideally, the entry criteria, baseline evaluation, response assessment, outcome measures, and follow up would be standardized across newly designed prospective clinical trials.

Proposal for a European randomised phase II study in Sclerosing Mediastinal Diffuse Large B-cell lymphoma.

Barcelona, March 4, 2004

Based on data collected in retrospective series, mediastinal DLCL has been identified as a distinct disease entity. During a workshop held in the context of the recent meeting in Barcelona a perspective study has been proposed aimed to clarify:

- the role of rituximab in combination with chemotherapy
- the significance of PET in measuring response and determining prognosis following chemoimmunotherapy
- the potential residual benefit of radiotherapy after chemoimmunotherapy

Objectives of the proposed study have been defined as:

- Gather material for histopathologic review and prospective studies of immunophenotype.
- Maximise response rate to initial therapy.
- Obtain prospective comparable data on different regimens.
- Prospectively use PET as a response endpoint to assess its applicability in a future study.
- Collect information on radiotherapy outcomes to inform a future randomised trial design.

Suggested design:

Parallel randomised phase II studies.

- R-CHOP q21 as standard arm in all
- Early dose-intensified regimens specified by collaborative groups as experimental arm
- Radiotherapy according to local protocols, with prospective data collection for PFS, OS

Primary end-point: PET negativity at completion of chemotherapy (with central review of PET data).

Power calculation on the basis of a 10% increase in PET negativity in the experimental arm (from 50-60%)

Finally...

During the meeting the IELSG group bylaws have been approved and a Board of Directors is constituting; you will soon find the final text in the IELSG website www.ielsg.org

The next group meeting will be held in Ascona on 2005, every other year the meeting will be organized in different European centers.

Last but not least, we would like to thank Emili Montserrat, Armando Lopez Guillermo and all the staff in Barcelona for the nice hospitality and their excellent organization of the meeting.

Kind regards

F. Cavalli, E. Zucca, A. Conconi, C. Morinini, M. Trovesi