

Dear Friends,

Please find below the 47th NEWSLETTER of the International Extranodal Lymphoma Study Group.

Current status of the IELSG trials

The total accrual of prospective, retrospective and biological IELSG trials has now reached more than 6400 patients.

Ongoing prospective clinical studies

IELSG 37 – A randomized, open-label, multicenter, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy after Rituximab containing chemotherapy regimens to patients with newly diagnosed Primary Mediastinal Large B-Cell Lymphoma (PMLBCL)

One hundred thirty-one patients have been enrolled in this study: 96 in Italy, 18 in Ukraine, 6 in Norway, 5 in Switzerland, 3 in UK, and 1 in Canada.

We are currently waiting for the activation of other centers in Europe (Poland and Czech Republic) and Asia (Korea).

The amendment of the study protocol that allows the randomization of patients with PET Deuille score 3 is active in many centers and we hope we will soon have its approval for all participating centers.

IELSG 38 – A phase II study of Chlorambucil in combination with subcutaneous Rituximab followed by a maintenance therapy with subcutaneous Rituximab in patients with extranodal marginal zone B-cell lymphoma of mucosa associated lymphoid tissue (MALT lymphoma)

The IELSG 38 trial will assess the safety and efficacy of the Chlorambucil plus Rituximab combination using a new formulation of Rituximab given subcutaneously, followed by a two-year maintenance treatment with subcutaneous Rituximab. This will be the first study to assess a maintenance treatment with rituximab in this patient population. Based on the statistical design, 112 patients will be enrolled in the study. The study is open in Italy, France and Switzerland

Nineteen patients have been enrolled up to now (10 in Italy, 8 in France and 1 in Switzerland).

IELSG 39 – International prospective phase 2 trial addressing the efficacy of first-line Chlamydomphila psittaci-eradicating therapy with protracted administration of doxycycline followed by eradication monitoring and antibiotic re-treatment at infection re-occurrence in patients with newly diagnosed Ocular Adnexal Marginal Zone Lymphoma (OAMZL)

The IELSG 39 study will assess the role of prolonged doxycycline treatment and re-treatment in case of Chlamydomphila psittaci re-infection in patients with ocular adnexal marginal zone lymphoma. The study is open in the Italian centers and at present, 22 of the expected 34 patients have been enrolled.

IELSG 36 – BRISMA – Bendamustine and Rituximab for the treatment of Splenic Marginal Zone Lymphoma. A phase II prospective study

The IELSG 36 study will assess safety and efficacy of the combination of Bendamustine and Rituximab as a first line treatment in patients with splenic marginal zone lymphoma. The study is open in France and Italy. Seventy-five patients have been enrolled so far and we expect to complete the accrual by the end of the year.

IELSG 30 – A phase II study of R-CHOP with intensive CNS prophylaxis and scrotal irradiation in patients with primary testicular diffuse large B-cell lymphoma

The phase II IELSG 30 study, after the recall of Depocyte, was recently re-opened in Italy.

Accrual is almost completed (only one patient is missing to reach the goal of 35 patients). Thanks to the first efficacy results, an amendment aiming to increase the sample size is under evaluation.

New prospective trials

IELSG 43 – High-dose chemotherapy and autologous stem cell transplant or consolidating conventional chemotherapy in primary CNS lymphoma - randomized phase III trial (MATRix)

The IELSG 43 protocol recently received the approval of the German competent authorities and has started accrual: 5 patients have been enrolled.

IELSG 42 – An international phase II trial assessing tolerability and efficacy of sequential Methotrexate-Aracytin-based combination and R-ICE combination, followed by high-dose chemotherapy supported by autologous stem cell transplant, in patients with systemic B-cell lymphoma with central nervous system involvement at diagnosis or relapse (MARIETTA regimen)

This protocol has recently been sent to the competent authorities in Italy in order to receive their approval. The study is expected to be open in Germany, Israel, Italy, Spain, Switzerland, The Netherlands and UK.

Clinical trial with completed accrual

IELSG 32 – Randomized phase II trial on primary chemotherapy with high-dose Methotrexate and high-dose Cytarabine with or without Thiotepa, and with or without Rituximab, followed by brain irradiation vs. high-dose chemotherapy supported by autologous stem cells transplantation for immunocompetent patients with newly diagnosed primary CNS lymphoma

The accrual is completed and data analysis has already been started.

Ongoing retrospective studies

IELSG 17 – Multi-institutional retrospective analysis of intravascular lymphomatosis

Sixty-eight patients have been enrolled in 7 countries: 33 in Italy, 7 in Spain, 4 in Australia, 3 in France Greece, Hungary, Israel and in the Netherlands, 2 Argentina and Switzerland, 1 in Belgium, Germany, Poland, Sweden and 1 the United States

IELSG 31 - A retrospective international study of primary extranodal follicular lymphoma

Two hundred seventy-four patients have been enrolled: 87 in Italy, 67 in the Unites States, 36 in Spain, 33 in Greece, 31 in Switzerland, 19 in UK and 1 in Argentina

IELSG 35 - A retrospective international study of primary extranodal lymphoma of female genital tract

Forty-seven patients have been included: 22 in Italy, 8 in Chile, 7 in Saudi Arabia, 4 in Argentina, 3 in Israel and Spain

The next meeting will be held in London (UK) on April 17-18, 2015.

Save the date!

More details will follow soon.

Kind regards

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