Report NCU grant

Report submission date: 16.3.2012

Main applicant: Peter de Nully Brown

Project title: Nordic Lymphoma Group: A Nordic collaboration to combat malignant lymphoma.

NCU grant received (€): 40 000

Project commencement and completion dates: For the year 2011. Grants given for several years previously

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1. Brief description of the project, written in a language understandable to non-scientists (Maximum length: 100 words)

The goals of the Nordic Lymphoma Group, to conduct research into the biology, epidemiology and treatment of malignant lymphoma in the Nordic countries have been pursued during 2011 by the continuing accrual to the portfolio of active research protocols including clinical and molecular research. Several large and innovative studies have been closed and await final analysis and publications during the years 2012 and 2013, e.g. large cell lymphoma group (CRY04-study), mantle cell lymphoma group (MCLIII-study)and T-cell lymphoma group (manuscript accepted for publication in Journal of Clinical Oncology. These studies are being replaced by follow-up studies by the respective working groups as detailed below.

2. Summarize the major findings of the project (Maximum length: 400 words)

Hodgkin Lymphoma

- The Hodgkin group has presented an abstract in the lymphoma meeting in Lugano, June 2011, on the results of the Nordic study of low and intermediate stages of Hodgkin lymphoma.
- Sweden, Norway and Denmark have joined an international study, RATHL, on advanced Hodgkin lymphoma focusing on the treatment adjustment according to early metabolic response measured by PET. Accrual to RATHL study is ongoing well.
- New chairman Dr Alexander Fosså presented new protocol suggestion in December 2011 for treatment of elderly patients with Hodgkin lymphoma.
- Based on the application and need for money earlier, the Hodgkin group was not allocated support from NCU for 2011.

Large cell lymphoma:

- CRY-04 study: Final analysis with the median follow-up of more than three years has been performed. Manuscript of the CRY-study is now ready to be submitted for publication. Two manuscripts on the biological studies based on the data collected in CRY-04 study have been submitted and the third manuscript is in preparation. Biological studies include array comparative genomic hybridizations in combination with exon-based transcriptome profiling, and analysis of the serum VEGF levels on survival. Other molecular substudies from CRY-04 material, including exome and RNA sequencing, tissue microarrays, and multiplex ELISAs from plasma, are ongoing.
- The PET study has included the planned 100 patients and the final analysis of the data has been completed in February 2012. The study group is working on the manuscript.
- CHIC study: A new phase II follow-up study for the CRY-04 protocol was finalized on December 2010, and is open for recruitment in all Nordic countries. The purpose is to test whether early CNS prophylaxis given at the beginning of therapy for young high risk DLBCL patients is feasible and could reduce the risk of CNS relapses. About 40 patients are recruited so far and the safety analysis will be performed during the year 2012. CHIC study will be open for three years. Material for biological studies is collected (blood and spinal fluid).

The fraction of the NCU grant 2011 allocated by the coordination group to the activities of the large cell group has been used for (i) statistics, (ii) meeting activities, (iii) laboratory reagents.

Indolent (low-grade Lymphoma:

- The EORTC/Intergroup study 206981: A manuscript on prolonged follow up and a study on the value of molecular analysis of microscopic residual disease are both published in Journal of Clinical Oncology.
- The second protocol on Rituximab + INF-α in low-grade NHL has been completed and the final analysis is ready. An abstract was presented orally in the Lugano meeting 2011. The indolent lymphoma group is working on the full manuscript. Several spin-off projects are ongoing: e.g. mRNA expression array with fresh-frozen tissue in collaboration with Andreas Rosenwald's laboratory. The data will be related to clinical data.
- *NLG-SAKK follicular protol:* A new randomised phase 2 study in collaboration with Swiss lymphoma group on upfront treatment for follicular lymphoma has been started in Switzerland and is now open in Norway and Sweden, and will soon start inclusion also in Denmark and Finland Other Nordic countries are working on the applications to the authorities. The protocol treatment is 4+4 Rituximab with or without lenalidomide. Translational research studies are planned.
- The NCU grant has been spent on molecular and immunohistochemical analysis of the two protocols on Rituximab +/- INF-α and meeting activities.

Mantle cell lymphoma:

- MCLII protocol: In addition to the manuscript published in Blood 2008 (ref 24), another two manuscripts have been published. One on minimal residual disease and one on predictive factors for response and survival (refs 23 and 24). An udate of the MCL2 study has been submitted to British Journal of Hematology.
- The MCLII is succeeded by the MCLIII. The results of this study are presently being analysed.
- The B-cell receptor characteristics of the Nordic MCL2 and MCL3 patients have been included in a large European collaborative analysis of BCR stereotype in MCL (Hadzimitriou et al 2011).
- A new phase I / II study on frontline therapy in elderly patients is open in the Nordic countries (MCL IV Lena-BeRit; bendamustin, rituximab, lenalidomide with a dose finding study of lenalidomide as the phase I part of the study). The study is recruiting well. Phase I has been concluded and presented in ASH 2011. Phase II is recruiting is planned to be concluded in 2013.

- A new study for high risk patients with mantle cell lymphoma is now open in all Nordic countries (MARIT study, core of treatment schedule is high dose cytarabine combined with rituximab and autologous stem cell transplantation consolidation)
- Several biological studies are planned on both ongoing studies with special emphasis on molecular response evaluation.
- NCU grant was spent on detection of minimal residual disease.

T-cell lymphoma:

- The T-01 study: After the publication of the German experience pointing at the occurrence of late relapses in T-cell lymphomas, a decision was taken to publish the final analysis of the NLG-T-01 study with a 5-year median follow-up time (data presented at the EHA 2009 were with 3½ year median follow-up). The analysis results were produced by the NLG statistician Harald Anderson, Lund. In 2011, abstract was presented in ASH meeting and the manuscript has been accepted for publication in Journal of Clinical Oncology.
- An abstract with a subset analysis of angioimmunoblastic TCL has been presented in the Lugano 2011 meeting (June 2011). The studies on biological aspects on the basis of the NLG-T-01 tissue samples have been started.
- The T-02 protocol (ACT-1 trial): After reopening of the trial, accrual has increased steadily and the number of adverse events dropped dramatically. The ACT-1 trial has recruited approximately 100 patients and the ACT-2 100 patients. With a cumulative number of 200 pts, the ACT trial is already now belonging to the top 3 largest trials ever performed in systemic PTCL. A poster on hematopoietic recovery after autologous stem cell reinfusion has been presented in the Lugano meeting 2011 and ASH 2011.

  The fraction of the NCU grant 2010 allocated by the coordinating group to the activities of the T-cell lymphoma group has been used for (i) meeting activities (clinicians and pathologists), (ii) statistics (UNI-C data management and conversion from the database to the NLG statistician) and (iii) submission fees for congress abstracts, (iv) laboratory reagents for immunohistochemistry and molecular biology.

CNS lymphoma:

CNS lymphoma protocol consists of a combined multiagent immunochemotherapy regimen based on HD-MTX and HD-Ara-C, intraspinal Depocyte and maintenance temozolomide therapy for responding elderly patients. The CNS lymphoma study was closed at the end of October 2010 after a successful accrual of 67 patients from 12 centers. The overall response rate (CR+PR) was 82.7%. Maintenance treatment was started in 15 of 27 elderly patients and is not completed for all patients as yet. The toxicity was mainly grade 3-4 infections occurring during neutropenia especially after HD-AraC. There were four treatment related deaths. CNS group is working on the manuscript which will be completed during the year 2012. CNS group is planning to join European CNS study protocol, discussions with Italian group on collaboration are ongoing.

Support distributed to the PCNSL group has been spent on data management, monitoring and submission fees for ASH meeting abstract.

Epidemiology group:

An observational study in chemotherapy regimens in adult Burkitt lymphoma has been performed, based on the Danish and Swedish lymphoma registry databases. Manuscript on this data has been completed and has been sent to a journal. Similar observational study in mantle cell lymphoma is initiated and will be concluded during 2012.

- Epidemiology group was not allocated support from NCU for 2011.

3. Describe how the project has increased our knowledge of the prevention, cause and/or cure for cancer (Maximum length: 150 words)

Lymphoid cancer – malignant lymphoma - is the tenth most frequent cancer in the Nordic countries, amounting to a total of 5000 cases annually. Malignant lymphoma, however, comprise many subentities, which in the WHO classification amounts to more than 20 different diseases, each with its own particular malignant phenotype, biology, and treatment option.

The Nordic Lymphoma Group has gained considerable insight into the planning and management of clinical studies with translational research aspects. The ”harvest” in term of new insight when running clinical studies is based on hard work over several years.

Among the major achievements of NLG during the last years are i) results from Mantle cell lymphoma protocol II which by many throughout the world is considered standard therapy today, ii) preliminary results from Hodgkin lymphoma trial for limited stage disease with the use of smaller radiation fields with lower doses resulting in less long term side effects while maintaining excellent survival and iii) results from two randomized first-line studies in indolent lymphomas showing excellent results with immunotherapy (antibody treatment with or without interferon) and iv) results from the T-cell lymphoma trial showing that induction chemotherapy with CHOEP-14 and autologous stem cell transplantation is an effective treatment schedule for this lymphoma subtype, which earlier has not had any clear widely accepted treatment strategy.

4. Outline how Nordic cooperation has added value to this project (Maximum length 100 words)

The number of cases of each subtype being diagnosed annually in each country may be small. In order to gain increased knowledge, large, homogeneously treated patient cohorts with a possibility for long-term follow-up are needed.

Nordic collaboration enables us to collect sufficient numbers, to study them clinically and molecularly, and to follow them prospectively and completely to gain highly relevant scientific new knowledge. Also, the Nordic group contributes substantially with patients to joint European randomised trials.

5. Publications resulting from this and previous grants

NORDIC LYMPHOMA GROUP LIST OF PUBLICATIONS 1999 – :

1. Jerkeman M, Johansson B, Akerman M, Cavallin-Stahl E, Kristoffersson U, Mitelman F. Prognostic implications of cytogenetic aberrations in diffuse large B-cell lymphomas. Eur J Haematol 1999 Mar;62(3):184-90.

2. Jerkeman M, Anderson H, Cavallin-Stahl E, Dictor M, Hagberg H, Johnson A, Kaasa S, Kvaloy S, Sundstrom C, Akerman M. CHOP versus MACOP-B in aggressive lymphoma--a Nordic Lymphoma Group randomised trial. Ann Oncol 1999 Sep;10(9):1079-86.
3. Rodriguez-Catarino M, Jerkeman M, Ahlstrom H, Glimelius B, Hagberg H. Residual mass in aggressive lymphoma--does size, measured by computed tomography, influence clinical outcome? Acta Oncol 2000;39:485-9.
4. Amini RM, Enblad G, Gustavsson A, Ekman T, Erlanson M, Haapaniemi E and Glimelius B. Treatment outcome in patients younger than 60 years with advanced stages (IIB-IV) of Hodgkin's disease: the Swedish National Health Care Programme experience. Eur J Haematol 2000;65:379-89
5. Jerkeman M, Kaasa S, Hjermstad M, Kvaloy S, Cavallin-Stahl E. Health-related quality of life and its potential prognostic implications in patients with aggressive lymphoma: a Nordic Lymphoma Group Trial Med Oncol 2001;18:85-94.
6. Osby E, Taube A, Cavallin-Stahl E, Hagberg H, Bjorkholm M. Reproducibility of tumor response evaluation in patients with high-grade malignant non-Hodgkin's lymphoma. Med Oncol 2001;18:137-40.
7. Messori A, Vaiani M, Trippoli S, Rigacci L, Jerkeman M, Longo G. Survival in patients with intermediate or high grade non-Hodgkin's lymphoma: meta-analysis of randomized studies comparing third generation regimens with CHOP Br J Cancer 2001;84:303-7.
8. Amini R-M, Glimelius B, Gustavsson A, Ekman T, Erlanson M, Haapaniemi E, Enblad G. A population-based study of the outcome for patients with first relapse of Hodgkin's lymphoma. Eur J Haematol 2002;68:225-232.
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11. Kimby E. Beyond immunochemotherapy: combinations of rituximab with cytokines IFN-α2a and G-CSF. Sem in Oncology 2002; 29: 7-10.
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13. Osby E, Hagberg H, Kvaloy S, Teerenhovi L, Anderson H, Cavallin-Stahl E, Holte H, Myhre J, Pertovaara H, Bjorkholm M. CHOP is superior to CNOP in elderly patients with aggressive lymphoma while outcome is unaffected by filgrastim treatment: results of a Nordic Lymphoma Group Randomized trial. Blood 2003;101(10):3840-8.
14. Linderoth J, Jerkeman M, Cavallin-Stahl E, Kvaloy S, Torlakovic E. Immunohistochemical Expression of CD23 and CD40 May Identify Prognostically Favorable Subgroups of Diffuse Large B-cell Lymphoma: A Nordic Lymphoma Group Study. Clin Cancer Res. 2003;9:722-8.
15. Molin D, Enblad G, Gustavsson A, Ekman T, Erlanson M, Haapaniemi E, Glimelius B. Early and intermediate stage Hodgkin's lymphoma – report from the Swedish National Care Programme. Eur J Haematol 2003;70:172-80.
16. Andersen NS, Pedersen, Elonen E et al for the Nordic Lymphoma Group. Primary Treatment with autologous stem cell transplantation in Mantle Cell Lymphoma. Outcome related to remission pretransplant but not to tumour cell contamination of the autograft. Eur J Haematol 2003;71:73-80.
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23. Andersen NS, Pedersen LB, Laurell A, Elonen E, Kolstad A, Boesen AM, Pedersen LM, Lauritzen GF, Ekanger R, Nilsson-Ehle H, Nordström M, Fredén S, Jerkeman M, Eriksson M, Väärt J, Malmér B, Geisler CH for the Nordic Lymphoma Group. Preemptive

treatment with rituximab of molecular relapse after autologous stem cell transplantation in mantle cell lymphoma. J Clin Oncol. 2009; 27: 4365-70.

24. Geisler CH, Kolstad A, Laurell A, Raty R, Jerkeman M, Eriksson M, Nordstrom M, Kimby E, Boesen AM, Nilsson-Ehle H, Kuittinen O, Lauritzsen GF, Ralfkiaer E, Ehinger M, Sundstrom C, Delabie J, Karjalainen-Lindsberg ML, Brown P, Elonen E. The Mantle Cell Lymphoma Prognostic Index (MIPI) is superior to the International Prognostic Index (IPI) in predicting survival following intensive 1st-line immunochemotherapy and autologous stem-cell transplantation (ASCT). Blood. 2010; 115: 1530-3.
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in a population based cohort of 505 patients with long follow-up times. Br J Haematol 2012;156:225-33.
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Manuscripts Submitted:

41. P.J. Lugtenburg PJ , Eriksson M, W. van Putten W, Holte H, Biesma DH, van Marwijk-Kooy M, Fijnheer R, Wijermans P, Steijaert M, de Jong D, Lam K, van Imhoff G, van Oers MHJ, Verhoef GEG, Sundström C , Huijgens PC, Sonneveld P for the Dutch HOVON group and the Nordic Lymphoma Group NLG. Two-weekly CHOP chemotherapy with or without rituximab for the treatment of diffuse large B-cell lymphoma in advanced stage poor-risk elderly patients: a randomized phase III trial by the Dutch HOVON and Nordic Lymphoma groups
42. Christian H. Geisler, Arne Kolstad, Anna Laurell, Mats Jerkeman, Riikka Räty, Niels S. Andersen, Lone B. Pedersen, Mikael Eriksson, Marie Nordström, Eva Kimby, Hans Bentzen, Outi Kuittinen, Grete F. Lauritzsen, Herman Nilsson-Ehle, Elisabeth Ralfkiær, Mats Ehinger, Christer Sundström, Jan Delabie, Marja-Liisa Karjalainen-Lindsberg, Peter Brown, and Erkki Elonen, for the Nordic Lymphoma Group. Nordic MCL2 Trial: Six-year follow-up after intensive immunochemotherapy for untreated mantle cell lymphoma followed by BEAM or BEAC + autologous stem-cell support. An update of phase-II multicenter study by the Nordic Lymphoma Group. Submitted, British Journal of Haematology

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45. Riihijärvi, S., Nyman, H., Holte, H., Björkholm, M., Fluge, Ø., Jyrkkiö, S., Pedersen, L.M., Jerkeman, M., Eriksson, M., and Leppä, S. High serum vascular endothelial growth factor level is an adverse prognostic factor for high risk diffuse large B-cell lymphoma patients treated with dose dense chemoimmunotherapy.
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