

Søknadsinformasjon

Utlysning	Nordic Cancer Union Research Grant, 2014
Søknad	Prolonged Bone Protection in Multiple Myeloma - the Magnolia Study.
Søknadsid	154677
Innsendt av	Niels Abildgaard

Oppgave: Progress report

Tilordnet	Niels Abildgaard
Status	Arkivert
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RAPPORT

Briefly describe the project in a language understandable to non-scientists

Multiple myeloma is the cancer that most frequently involves the bones, causing fractures. Treatment with bisphosphonates can inhibit the advancement of bone disease and is therefore used in multiple myeloma as well as in metastatic bone disease, e.g. breast and prostate cancer. In multiple myeloma, bisphosphonates were approved based on trials where patients were treated for two years. Until recent years it has been daily praxis to continue treatment indefinitely. However, observations of development of osteonecrosis of the jaw in up to 5-10 % of patients treated for more than 2 years has raised questions about the risk-benefit relationship of continued treatment.

We investigate 3 questions:

1. Should prophylactic treatment with bisphosphonate continue more than two years?
2. Are CT-scans better than conventional X-rays?
3. Is it possible to monitor the bone disease in individual patients by use bone markers in serum thus initiating treatment before bone disease becomes apparent?

Summarize the major findings of the project

The project has been approved by all authorities and initiated in all three Scandinavian Countries. 23 Sites throughout the region have agreed to participate; 7 in Denmark, 7 in Norway, and 9 in Sweden. Patients have been included in Denmark and Norway, and a total of 20 patients have been included. We have since the original application received a grant from the Danish Organization "Kræftens Bekæmpelse" on 750,000 Danish Crowns to cover some of the expenses concerning measurements of bone markers.

Summary: After a bit delay in starting up the participating sites, the project is progressing acceptably, patients are in inclusion process and data are being sampled.

Describe how the project has increased our knowledge of the prevention, cause and/or cure for cancer

Once finalised we expect this study to answer 3 important questions:

1. Should prophylactic treatment with bisphosphonate continue more than two years? Patients are randomized to receive either 2 or 4 years of treatment. The study will clarify if there is a benefit for the patients in having less bone fractures without having significantly higher risk of osteonecrosis of the jaw. This question is sup
2. Are CT-scans better than conventional X-rays? Traditionally, bone disease is monitored by the use of X-rays. We hypothesize that CT-scans are more sensitive and will be able to detect bone disease earlier, so that relevant treatment can be initiated earlier. Patients will have both investigations performed, so we can determine which test is better.
3. Is it possible to monitor the bone disease in individual patients by use bone markers in serum? When bone matrix is degraded, specific peptides derived from collagen type I are liberated and can be measured in blood. We have data showing that the concentration in blood of these collagen type I split products increases, prior to the development of bone new bone lesions. We will validate these findings in a prospective study. If confirmed, bone markers will be a valuable tool in monitoring bone disease and for guidance of bone treatment.

Outline how Nordic cooperation has added value to this project

Multiple Myeloma is a rare disease with an annual incidence of 6/100,000. It would not be possible to conduct this trial in the single countries. Nordic Myeloma Study Group has performed clinical trials for more than 25 years and our organisation has made it possible to conduct a randomised study.

Furthermore, the support from the Nordic Cancer Union makes it possible to perform this study that is commercially without interest for pharmaceutical companies. For daily care and for the patients it is highly relevant.

Brief overview of expenditures for last year 1 vedlegg (Copy of expenses 2015 for NCU grant 2014.xlsx)