EUMDS Registry Newsletter

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Hello!

We would like to welcome you to our EUMDS newsletter number 4.
To subscribe/unsubscribe to the EUMDS Registry Newsletter, please send a mail to: j.droste@hemat.umcn.nl with the word "Subscribe" or "Unsubscribe" in the subject line.

Send Your Suggestions

Is there anything you'd like to see in the next newsletter? We'd like to hear from you! Please contact us if you have any suggestions, questions, or comments concerning any of the topics described in this Newsletter and on the Registry in general either by emailing Jackie Droste at **j.droste@hemat.umcn.nl** or calling at **+31 24 3614794**.

Inclusion

At the end of June 44 patients have been included in the registry, of whom one died. 18 Different sites in 9 countries included at least 1 patient. At the end of June 93 sites were ready to start inclusion of patients, or already included patients.

Drug related therapy

The Steering Committee will allow the use of hypomethylating agents (5-azacitidine and Decitabine) as single agents or in combination with histone deacetylase inhibitors and/or All trans retinoic acid (ATRA). Patients currently eligible for such therapy are likely to be only a small number, typically (but not exclusively) INT-1 with 5-10% blasts. Other active therapies such as erythropoietic stimulating agents, thalidomide, Antithymocyte globulin and lenalinomide are also allowed.

Sub studies

During the last Steering Committee meeting a number of sub studies were discussed. For each sub study mentioned below a protocol will be distributed before the next Steering Committee meeting and the sub studies will be discussed again.

- Central morphology review
  The proposal is to a review 10% of the bone marrow slides of all patients (=100 slides) by a number of review centres to establish the quality of the database and the reproducibility of the data. The responsibility of the patients will remain at the site the patient visits.

- Cardiac Evaluation
  Proposal is a standardized evaluation of heart and liver by an MRI/T2* for a number of patients.

- Serum proteomic profiling
  This is implemented in the registry already; extra blood/urine is collected (see also Sample Record Forms)

- Co Morbidity
  To establish comorbidity a number of parameters is used, which are probably all collected in the database already.

- Iron parameters
  Systematic measurement of iron parameters:
  □ ferritin, NTBI, erythropoietin
  □ serum hepcidin
  □ soluble transferrin receptor (sTfR)
  □ GDF-15, HFE gene mutation
  Organ toxicity:
  □ cardiac and liver MRI
  □ LVEF (echocardiography)
  □ bone marrow aspirate and biopsy

Important: Investigator Site File (ISF)

During the operational team teleconference attention has been paid to the Investigator Site File again. It is important that each participating site maintain his Investigator Site File, which can be obtained at the coordinator of each country. The content should be kept up to date and the forms

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described in the manual of procedures must be filled up. For example curriculum vitas of the study team are supposed to be kept in the ISF, a screening log has to be maintained as is the patient identification form. When a monitor visits your site for quality control, the monitor will check your investigator site file for completeness. Whenever there are any questions regarding the ISF please contact your coordinator.

Meetings

The next Steering Committee meeting will be the 6th of September 14.00-17.00 in Prague. One of the main topics will be the accrual of the study, the extension of the study to more registries, and the continuation of the study (>1000 patients).The next Operational Team meeting will be the 6th of September 10.00-13.00 in Prague. There will be a joined lunch for both teams from 13.00-14.00.
The third Monday of each month from 16.00 to 16.45 h a teleconference for the operational team is scheduled. (Except for July due to holiday season)

Sample Record Forms

For patients from whom additional blood and urine is collected for biological correlative studies, sample record forms should be completed... Please be as accurate as possible when recording the times and ensure that any deviations are noted. Once completed, copies of these forms should be faxed to Lorna Barnard the UK Coordinator on +44 113 2067468. The original form should be kept in the Investigator Site File.

Organisation of the Netherlands

Manita Bremmers, trial coordinator, Trial Coordination and Datacenter (TDC) of the department of Haematology, Radboud University Nijmegen Medical Centre Nijmegen (RUNMC), the Netherlands

Since 1996, a regional MDS registry was set up between RUNMC and 18 cooperating sites in the south eastern part of The Netherlands. Until now approximately 800 patients are included. In 2006 the MDS-registry was reorganized and an amendment was activated. This protocol emphasises the integration of clinical data, morphology, and since then also histology and cytogenetics. Important part of the registry is the central review of smears and biopsies for quality control reasons.

The EUMDS registry will be setup in the already existing and established network.
The RUNMC EUMDS and regional MDS registry team consist of the same 5 experienced members Dr. M. MacKenzie MD, haematologist, M. Berends, MD trainee haematologist, N. van Wijngaarden, data manager, E. Voorbrood laboratory technician and M. Bremmers as trial coordinator.
Patients in the RUNMC are diagnosed as MDS by the morphology laboratory and by the haematologists. The trial coordinator receives information and sends the documents to the treating physician of the patient. The physician informs the patient about the diagnosis and MDS registry. After receiving the signed informed consent the patient will be registered by the data manager.
It is decided to make the following arrangements with the participating sites including the university hospital of Amsterdam. For these sites there are 3 possibilities:

- Informed consent procedure and CRF data entry is performed by the local site
- Informed consent is taken care of by local site and CRF data entry is performed by referral site in Nijmegen.
- Patient will be referred once to referral site in Nijmegen. Informed consent procedure is taken care by referral site in Nijmegen and the CRF data entry will be performed in one of both ways.

In April the first patient was included and the team is ready to welcome the other 49.