

EUMDS Registry Newsletter



Table of contents

- Hello!
- Send Your Suggestions
- Inclusion
- Database
- Accrual
- Drug related therapy
- Meetings
- Screening log form
- Organisation of United Kingdom
- Sub study: Iron overload in MDS

Hello!

We would like to welcome you to our EUMDS newsletter number 5.

To subscribe/cancel to the EUMDS Registry Newsletter, please send a mail to:

j.droste@hemat.umcn.nl with the word "Subscribe" or "Cancel" 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 September 136 patients have been included in the registry, of whom one died. 42 Different sites in 10 countries included at least 1 patient.

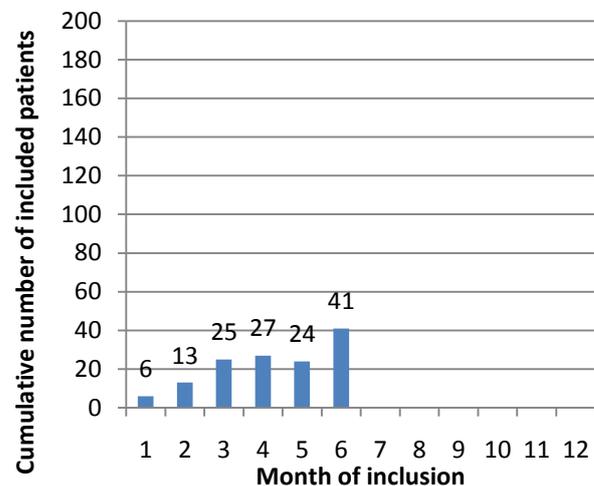
Database

A new release of the database is planned the 10th of October, which means that the website is unavailable this day. This new release will include warnings.

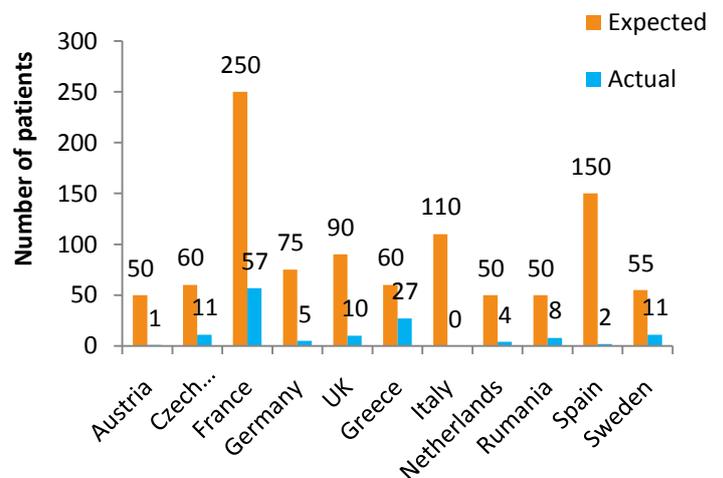
There will be several kinds of warnings: for example laboratory results which are too low or too high will result in a warning. These warnings can be seen in the recruitment summary window and accessed by clicking on it. Subsequently the warning can be approved or cleared. Furthermore all warnings of a country will be send to the country coordinator by email. At the centre administration page, email addresses can be added or removed to whom these warnings should be sent.

Accrual

Overall accrual per month



Accrual per country



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Table of contents

Hello!
 Send Your Suggestions
 Inclusion
 Database
 Accrual
 Drug related therapy
 Meetings
 Screening log form
 Organisation of United Kingdom
 Sub study: Iron overload in MDS

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.

Meetings

The next Steering Committee meeting will be early February 2009 in Mannheim and a teleconference is scheduled the 17th of November 18.00-19.00 CET.

The next Operational Team meeting will also be early February 2009 in Mannheim. Teleconferences will be scheduled once the new database has gone live and is used for at least 2 weeks.

Screening log form

All clinical sites have to maintain an Investigator Site File, including the screening log form. Data for each patient that is screened and may be entered into the study should be entered into the screening log form.

Organisation of United Kingdom

Lorna Barnard, ELN Registry Coordinator Clinical Trials
 Department of Haematology
 St James University Hospital
 Leeds
 UK

The EUMDS Registry involves 20 centres across the UK. It is coordinated centrally in Leeds but each centre has its own trial team including

coordinators, research nurses, and principle investigators. In Leeds the team consists of Dr David Bowen (Principle Investigator), Dr Anne Critchley (Co investigator), Louise Arnold (Research Nurse) and Lorna Barnard (Registry Coordinator). Each centre is responsible for its own informed consent procedure and the data collection and entry onto the database with assistance if necessary from Leeds.

Once a centre has all the required approvals in place they have an initiation meeting and can then start recruiting patients. To date 6 centres in the UK are open to recruitment and a number of others will be shortly. Our first patient was registered in June and we have now just registered the 11th. Hopefully we are on track to recruit all 90 patients by the end of the enrolment period.

So far all centres in the UK are collecting the blood and urine samples for the registry. Some centres process and store these themselves, some process them and send them to Leeds for storage and the rest send them to Leeds for both processing and storage. All centres forward a copy of the sample record form via fax to the coordinators office in Leeds. I am responsible for the collection of the sample records forms for the whole project. Therefore I would be grateful if all centres storing samples would fax me a copy of the sample record form. We hope to perform global proteomic analysis of this large cohort of serum samples.

Sub study: Iron overload in MDS

A new dimension for the registry will be the planned sub studies. As written in newsletter 4, iron overload in MDS may be one of the new sub studies.

Iron accumulation is not only a result of iron overload due to transfusions, but also caused by increased intestinal iron absorption due to ineffective erythropoiesis. (See schematic picture presented for the iron sub study)

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- Screening log form
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UMC St Radboud

Iron accumulation in MDS patients due to stimulation of intestinal iron uptake by ineffective erythropoiesis

