Iron overload in MDS patients: the value of new iron parameters and MRI T2* of heart and liver as predictor of iron overload

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational invasive

Summary

ID

NL-OMON36112

Source
ToetsingOnline

Brief title
Iron overload in MDS patients

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)
- Heart failures

Synonym
Myelodysplastic syndrome -> bone marrow disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Novartis,Novartis Pharma BV Nederland;6900 LZ Arnhem;Postbus 241.

Intervention

Keyword: iron overload, MDS, MRI T2*

Outcome measures

Primary outcome

Serum iron, serum ferritin, transferrin saturation level, hepcidin, GDF15 and

sTfR.

Iron overload as assessed by MRI T2* heart and liver and left ventricular

function by echocardiography.

Secondary outcome

Not applicable.

Study description

Background summary

Title of the study:
Iron overload in MDS patients: the value of new iron parameters and MRI T2* of heart and liver as predictor of iron overload.

Background of the study:
Patients with MDS often develop anemia and become transfusion-dependent in the course of the disease. Frequent blood transfusions cause iron overload, especially in the heart and the liver. Iron overload has significant clinical consequences, including liver cirrhosis and heart failure, with increased morbidity and mortality. Iron overload in MDS patients is mainly caused by blood transfusions but can also be the result of an ineffective erythropoiesis. The pathophysiological mechanisms of iron overload and subsequent organ dysfunction are largely unknown. The occurrence of iron overload is frequently not recognized or only at a late stage. Nowadays, prevention and treatment of

iron overload and its complications is possible by new iron chelating agents.

Study objective

The aim of the current study is to improve the diagnosis of iron overload in MDS patients. The primary objectives are to evaluate 1. the relationship between red blood cell transfusions and iron overload in liver and heart as investigated by MRI T2* in MDS patients and 2. the relationship between the iron parameters (serum ferritin and transferrin saturation level) and iron overload as investigated by MRI T2* in blood transfusion dependent MDS patients. The secondary objectives are to determine evidence for iron overload in blood transfusion-dependent and independent MDS patients due to ineffective erythropoiesis by measuring iron parameters like serum iron, serum ferritin, transferrin saturation level, hepcidin, GDF15, sTfR and MRI T2* (liver and heart).

Study design

The study is a prospective, multicenter, non-randomized and non-interventional investigation.
The study is performed in 75 patients from the Radboud University Nijmegen Medical Center and participating hospitals in the IKO and IKZ region. The inclusion period is 3 years with 3 year follow-up for each patient. The following investigations will be performed at inclusion and once yearly during follow-up: MRI T2* heart and liver and echocardiography. Every six months a blood sample of 20mL will be collected (simultaneously with regular blood sampling) to determine specific iron parameters.

Intervention

Protocol pg. 14, 15

- MRI T2* liver: liver iron content
- MRI T2* heart: myocardial iron content and ejection fraction
- Echocardiography: evaluation of the left ventricular diastolic function

Study burden and risks

MRI and echocardiography at inclusion and once yearly during follow-up.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Theodoor Craanenlaan 1
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Theodoor Craanenlaan 1
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with MDS according to WHO 2001-criteria (RA, RARS, RAEB-1, RAEB-2, RCMD, RCMD-RS, MDS with isolated del(5q), MDS-U).
- Patient with IPSS low-risk, intermediate-1 or intermediate-2 risk.
- Untreated patients or patients treated with blood transfusions, growth factors, iron chelation therapy, the immunomodulatory drug lenalidomide or the hypomethylating agents azacitidine or decitabine.
- Informed consent and of legal age at the time of obtaining informed consent (*18yrs).

Exclusion criteria

- Patients with previous intensive anti-leukemic therapy (intensive chemotherapy and/or stem cell transplantation).
- Patients with secondary or therapy-related AML and MDS after chemotherapy for a malignancy or radiotherapy.
- Patients with IPSS high risk MDS.
- Patients with a contraindication for MRI: Metal body parts, internal defibrillator, pacemaker, neurostimulator, bladder stimulator, insulin pump, cochlear implant, claustrophobia or

another reason that prohibits MRI evaluation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2011
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	10-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35915.091.11