IJzerstapeling bij patiënten met MDS: De waarde van nieuwe ijzerparameters en MRI als voorspeller van ijzerstapeling.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27359

Source
NTR

Brief title
PIRON01

Health condition

Myelodysplastic syndrome (MDS)

Sponsors and support

Primary sponsor: University Medical Centre NIjmegen
Departmetn of Hematology
Source(s) of monetary or material Support: Novartis, The Netherlands

Intervention

Outcome measures

Primary outcome

A relationship between T2*Liver and or T2*Heart levels and the number of blood transfusions.

Secondary outcome

Evidence for iron overload in transfusion-independent and transfusion-dependent MDS patients due to ineffective erythropoiesis.

Study description

Background summary

This is a prospective study in MDS patients with IPSS low-risk, intermediate-1 or intermediate-2 risk. Information will be gathered at the entry of the study and during follow-up visits scheduled for routine patient care.

Primary objectives:

To evaluate the relationship between red blood cell transfusions and iron overload in liver and heart as investigated by MRI T2* in MDS patients.

To evaluate 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.

Secondary objectives:

To determine evidence for iron overload in transfusion-independent MDS patients due to ineffective erythropoiesis (serum iron, serum ferritin, transferrin saturation level, hepcidin, GDF15, sTfR and MRI T2*).

To determine evidence for iron overload in blood transfusion dependent MDS patients due to ineffective erythropoiesis (serum iron, serum ferritin, transferrin saturation level, hepcidin, GDF15, sTfR and MRI T2*).

Exploratory objectives:

To evaluate the effect of iron chelation therapy on the iron parameters and iron overload as investigated by MRI T2* (liver and heart) and to determine the best cut-off point to start iron chelation therapy.

To evaluate the relationship between the left ventricular diastolic function by echocardiography and iron overload in blood (serum iron, serum ferritin, transferrin saturation level, hepcidin, GDF15, sTfR) and iron overload as investigated by MRI T2*.

To determine if the presence of the HFE gene mutation has any influence on the severity of iron overload.

Study design:

Prospective, multicenter.

Duration:

3 years inclusion, 3 years of follow-up per patient.

Study objective

The hypothesis to be tested is the relationship between the number of blood transfusions, serum ferritin and transferrin saturation level and MRI T2*Heart, T2*Liver.

Study design

1. At inclusion;

2. During follow-up: Every 6 months.

Intervention

No interventions.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with MDS according to WHO 2001-criteria (RA, RARS, RAEB-1, RAEB-2, RCMD, RCMD-RS, MDS with isolated del(5q), MDS-U);

2. Patient with IPSS low-risk, intermediate-1 or intermediate-2 risk;

3. Untreated patients or patients treated with blood transfusions, growth factors, iron chelation therapy, the immunomodulatory drug lenalidomide or the hypomethylating agents azacitidine or decitabine;

4. Informed consent and of legal age at the time of obtaining informed consent (≥18yrs).

Exclusion criteria

1. Patients with previous intensive anti-leukemic therapy (intensive chemotherapy and/or stem cell transplantation);

2. Patients with secondary or therapy-related AML and MDS after chemotherapy for a malignancy or radiotherapy;

3. Patients with IPSS high risk MDS;

4. Patients with a contraindication for MRI: Gadolinium allergy, impaired kidney function (MDRD <45 mL/min/1.73m2), metal 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 non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-06-2011
Application type:	First submission

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
NTR-new	NL2810

Register	ID
NTR-old	NTR2951
Other	CMO Arnhem-Nijmegen : 2011/122
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A