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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27359

Bron
NTR

Verkorte titel
PIRON01

Aandoening

Myelodysplastic syndrome (MDS)

Ondersteuning

Primaire sponsor: University Medical Centre NIjmegen
Departmetn of Hematology
Overige ondersteuning: Novartis, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. At inclusion;

2. During follow-up: Every 6 months.

Onderzoeksproduct en/of interventie

No interventions.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2810
NTR-old	NTR2951
Ander register	CMO Arnhem-Nijmegen : 2011/122
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A