Characterizing the bone marrow environment in advanced-stage myelofibrosis. A PET/MRI study.

Gepubliceerd: 19-06-2015 Laatst bijgewerkt: 13-12-2022

We hypothesize that by using different imaging techniques, we can give a good characterization of the bone marrow microenvironment in advanced-stage myelofibrosis, before and during treatment with ruxolitinib.

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

Samenvatting

ID

NL-OMON20797

Bron
Nationaal Trial Register

Verkorte titel
BEAMY

Aandoening

Myelofibrosis. Myelofibrose.
Ruxolitinib.
PET
MRI

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Novartis Pharma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A detailed description of the bone marrow environment in advanced-stage myelofibrosis at baseline and during treatment, using the following parameters:
- Histopathological findings on bone marrow biopsy
- Functional parameters:
-- Perfusion (15O-water PET/CT)
-- Perfusion/permeability (MRI-DCE)
-- Osteoblastic activity (18F-fluoride PET/CT)
-- Diffusion restriction (MRI-DWIBS)
- Conventional treatment response evaluation according to IWG consensus criteria

Toelichting onderzoek

Achtergrond van het onderzoek

In myelofibrosis, it is not yet completely understood how the pathologic alterations in the bone marrow environment evolve. After long-term treatment with ruxolitinib – the present standard therapy for patients with advanced-stage myelofibrosis –, regression of marrow fibrosis has been demonstrated in several patients. The currently used diagnostic tool - the bone marrow biopsy – is however not sensitive enough to detect early and functional changes. In this study we aim to gain more insight into the bone marrow microenvironment in advanced-stage myelofibrosis and changes herein during ruxolitinib treatment, by using well-known imaging techniques. More specifically, we will evaluate osteoblastic activity and bone marrow perfusion and – diffusion characteristics using 15O-water-PET, 18F-Fluoride-PET and MRI-DCE and –DWIBS. Furthermore, bone marrow biopsies will be performed in order to assess histopathological response.

Doel van het onderzoek

We hypothesize that by using different imaging techniques, we can give a good characterization of the bone marrow microenvironment in advanced-stage myelofibrosis, before and during treatment with ruxolitinib.

Onderzoeksopzet

At entry, after 6 and 18 months of treatment.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- A diagnosis of primary MF, post-PV MF or post-ET MF according to the 2008 WHO criteria.

- High- or intermediate-1 or -2 risk level according to the IWG-MRT IPSS criteria

- High grade fibrosis (grade 3 or 4) on bone marrow biopsy

- A scheduled treatment with (and thus an indication and eligibility for) ruxolitinib

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Current or previous treatment with a JAK2 inhibitor

- History of allogeneic stem cell transplantation

- Contraindication for treatment with ruxolitinib (including a platelet count < 50,000/µL)

- Contraindication for used imaging modalities

- Inability to sign informed consent

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2015
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	NL5127
NTR-old	NTR5259
Ander register	METC VUmc : 2014.479

Resultaten

Samenvatting resultaten
Not applicable