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

No registrations found.

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

Summary

ID

NL-OMON20797

Source
Nationaal Trial Register

Brief title
BEAMY

Health condition

Myelofibrosis. Myelofibrose.
Ruxolitinib.
PET
MRI

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Novartis Pharma

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Exploration of the best imaging technique in diagnosis and response monitoring during ruxolitinib treatment

- Explore the degree of sampling error of bone marrow biopsies in myelofibrosis

Study description

Background summary

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.

Study objective

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.

Study design

At entry, after 6 and 18 months of treatment.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	6
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-06-2015
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	NL5127
NTR-old	NTR5259
Other	METC VUmc : 2014.479

Study results

Summary results
Not applicable