A phase II trial in patients with myelofibrosis (primary, post-ET or post PV-MF) treated with the selective JAK2 inhibitor Pacritinib before reduced-intensity conditioning allogeneic stem cell transplantation

Gepubliceerd: 09-03-2017 Laatst bijgewerkt: 13-12-2022

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21596

Bron
NTR

Verkorte titel
HOVON 134 MF

Aandoening

Myelofibrosis, primary, post-ET, post PV-MF

Allogeneic stem cell transplantation

Myelofibrose

Allogene stamceltransplantatie

Ondersteuning

Primaire sponsor: HOVON

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Overige ondersteuning: HOVON; Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint
♦ Proportion of patients receiving allo-SCT, with failure within or at day 180 post-transplant. Events that are considered a failure are:
o Primary graft failure
o Acute graft versus host disease grade 3-4
o Secondary graft failure
o Death, from any cause

Toelichting onderzoek

Achtergrond van het onderzoek

Study design: Phase II, single arm, multicentre

Study objectives: The effect of pacritinib treatment during 3 to 4 cycles before allo-SCT on engraftment 6 months (day +180) post allo-SCT in MF patients.

Rationale: The only curative treatment for patients with myelofibrosis (MF) is allogeneic stem cell transplantation (SCT). Treatment with JAK2 inhibitors like pacritinib improves condition of MF patients, decreases spleen size and might diminish graft-versus-host disease (GvHD), thereby improving the outcome of SCT.

Onderzoeksopzet

Time of clinical evaluations

♦ Before enrollment: within 6 weeks before registration

♦ During pacritinib treatment biweekly in the first month and thereafter monthly

♦ Before allo-SCT: 1 or 2 weeks before allo-SCT

♦ After allo-SCT: 1, 2, 3, 4, 6, 9, and 12 months after allo-SCT

Onderzoeksproduct en/of interventie

Induction with 3-4 cycles pacritinib, followed by allo-SCT if suitable donor available. All patients will receive the same treatment.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- Patients with a confirmed diagnosis of post-ET, post-PV or primary myelofibrosis (Appendix A)

- Intermediate-2 or high-risk according to DIPSS plus (Appendix E)

- Age 18-70 years inclusive

- WHO performance status 0-2 (Appendix C)

- At least 1 week since prior treatment (most recent dose) with a potent cytochrome P450 3A4 (CYP3A4) inhibitor

- All men and women of childbearing potential must agree to use adequate contraception during the study

- Written informed consent

- Patient is capable of giving informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous treatment with JAK2 inhibitors within 2 weeks of study inclusion. Patients who have been treated with pacritinib as their previous JAK2 inhibitor treatment cannot participate in this study

- Any GI or metabolic condition that could interfere with absorption of oral medication

- Severe cardiac dysfunction (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease)

- Experimental treatment within four weeks before inclusion for PMF, Post-PV, or Post-ET MF

- Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D)

- Significant hepatic dysfunction (total bilirubin ≥ 30 µmol/l

or transaminases ≥ 3 times normal level, unless disease-related)

- Severe neurological or psychiatric disease

- Severe renal impairment (creatinine clearance < 40 ml/min)

- Patients with active, uncontrolled infections

- Patients known to be HIV(human immunodeficiency virus)-positive

- Active hepatitis A, B or C

- History of active malignancy during the past 3 years, except basal carcinoma of the skin or stage 0 cervical carcinoma

- Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension, cancer, etc.)

- Pregnant or breastfeeding women

- Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-03-2017
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	NL6578
NTR-old	NTR6751
Ander register	: MEC-2015- 750

Resultaten