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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21596

Source
Nationaal Trial Register

Brief title
HOVON 134 MF

Health condition

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

Allogeneic stem cell transplantation

Myelofibrose

Allogene stamceltransplantatie

Sponsors and support

Primary sponsor: HOVON

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Source(s) of monetary or material Support: HOVON; Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoints

♦ Adverse events

♦ Proportion of patients receiving allo-SCT

♦ Response rate (≥ PR) (see appendix B)

♦ Progression free survival (PFS, i.e. time from either registration or allo-SCT until progression/relapse or death from any cause, whichever comes first)

♦ Overall survival (OS) calculated from either registration or allo-SCT. Patients still alive or lost to follow up are censored at the date they were last known to be alive

♦ Relapse mortality (RM), i.e. death due to the disease or after progression

♦ Non-relapse mortality (NRM)

♦ Quality of Life during/after treatment

Study description

Background summary

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2017
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	NL6578
NTR-old	NTR6751
Other	: MEC-2015- 750

Study results