Response and Adherence to Nilotinib in Daily Practice

No registrations found.

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

Summary

ID

NL-OMON23279

Source
Nationaal Trial Register

Brief title
RAND-study

Health condition

chronic myeloid leukemia

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam
Source(s) of monetary or material Support: Novartis, the Netherlands

Intervention

Outcome measures

Primary outcome

1. MMR within 12 months after the start of first study medication.
2. Adherence: the total intake of nilotinib capsules as counted by means of a MEMS taken as percentage of the number of pills prescribed over the 12 months follow-up period.

Secondary outcome

Rates of complete hematological response (CHR; the normalization of the blood cell count), CCyR (complete absence of Ph+ cells in blood and bone marrow), and complete molecular response (CMR)(using RQ-PCR Ph+ DNA cannot be detected); trough plasma level of nilotinib; potential drug-drug interactions; patient-reported side effects; adherence by means of telephonic pill count; adherence behaviour by means of the Medication Adherence Rating Scale (MARS); quality of life by means of the SF-12 Health Survey; attitude towards disease and medication by means of the Brief Illness Perception Questionnaire (IPQ) and the Beliefs about Medicines questionnaire (BMQ), resp.; patients' appreciation of information received about the medication by means of the Satisfaction with Information about Medicines Scale (SIMS); percentage of dose adjustment; patient-reported discontinuation; and patient demographics.

Study description

Background summary

23-mei-2014:

Background

The antitumor drug nilotinib has a large inter- and intra individual variability in pharmacokinetics. Adherence to treatment may substantially influence plasma levels and has been recognized as the most important determinant of treatment failure in chronic myeloid leukemia (CML). A better understanding of the various factors contributing to the efficacy of treatment is essential for the development of interventions to optimize the treatment of chronic phase CML (CP-CML) with a protein kinase inhibitor like nilotinib.

Methods/Design
In this multicenter prospective observational cohort study 70 adult patients with CP-CML starting treatment with nilotinib will be followed up for at least 12 months. Response to treatment is evaluated after 3, 6 and 12 months. Adherence is primarily assessed by counting the daily intake of nilotinib capsules by means of a medication event monitoring system (MEMS). Before the start of nilotinib treatment and after 3, 6 and 12 months, patients are asked to fill in a comprehensive questionnaire including topics on quality of life, side effects, attitude towards disease and medication, the patients' appreciation of information received about the medication, and discontinuation, and trough plasma levels of nilotinib are measured.

Study objective

The present study aims to get more insight into the efficacy of treatment with nilotinib and the various aspects that govern optimal response, of which adherence is a primary endpoint.

We hypothesize that patients who experience inadequate response levels to nilotinib are less adherent. In addition, their plasma levels of nilotinib may be lower.

Study design

Baseline and after 3, 6 and 12 months of treatment.

Intervention

CP-CML patients starting treatment with nilotinib are followed up for at least 12 months.

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female patients ≥ 18 years of age;
- ECOG 0, 1, or 2;
- Diagnosis of chronic myelogenous leukemia in chronic phase with cytogenetic confirmation of Philadelphia chromosome of (9;22) translocations;
- Starting treatment with nilotinib.

Exclusion criteria

- Patients who are considered Ph negative because they do not have a confirmed cytogenetic diagnosis of Philadelphia chromosome of (9,22) translocation;

- Previously documented T315I mutations;

- Treatment with tyrosine kinase inhibitor(s) prior to study entry is not allowed, except in the following situation: in emergent cases where the patient requires disease management while awaiting study start, commercial supplies of Glivec at any dose may be prescribed to the patient but for no longer than 2 weeks in duration;

- Any medical treatment for CML prior to study entry for longer than 2 weeks with the exception of hydroxyurea and/or anagrelide ;

- All other criteria based on the treatment guidelines.
- Inability to grant 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:	Recruitment stopped
Start date (anticipated):	01-05-2013
Enrollment:	70
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-05-2013

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41699
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3805
NTR-old	NTR3992
CCMO	NL41762.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41699

Study results

Summary results
Boons CCLM, Swart EL, Timmers L, Janssen JJWM, van de Ven PM, Hugtenburg JG. Study protocol of the RAND-study: a multicenter, prospective cohort study investigating response and adherence to nilotinib treatment in chronic myeloid leukemia. BMC Cancer 2014, 14:247.