Response and Adherence to Nilotinib in Daily Practice

Gepubliceerd: 14-05-2013 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON23279

Bron
NTR

Verkorte titel
RAND-study

Aandoening

chronic myeloid leukemia

Ondersteuning

Primaire sponsor: VU University Medical Center Amsterdam
Overige ondersteuning: Novartis, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

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 gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-05-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41699
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.