Effect van voedsel op de farmacokinetiek van nilotinib: op maat naar een lagere dosering (NiFo-onderzoek)

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23914

Source
NTR

Brief title
NiFo-study

Health condition

Chronic Myeloid Leukemia
Nilotinib

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The difference in pharmacokinetic parameters AUC, Cmax, and Cmin between fasted and fed administration of nilotinib.

Secondary outcome

Interpatient variability
Intrapatient variability
Patient-reported side effects
Quality of life

Study description

Background summary

Primary Objective: To evaluate the effect of real-life food consumption on the pharmacokinetics of nilotinib in CML patients.
Exploratory Objective: To evaluate patient reported side effects and quality of life of CML patients using nilotinib at a lowered dose of 200 mg bid, administered with a meal.

Study design: Intervention study with a pre-test post-test design, in chronic phase CML patients using nilotinib at a dose of 300 mg bid. The AUC, Cmax and Cmin of nilotinib, administered as recommended on an empty stomach during a period of four days, will be compared with the AUC, Cmax and Cmin of nilotinib 200 mg bid, administered with a meal for a period of seven days. Patient will be instructed about their meals. The study is non-invasive: nilotinib concentrations will be measured by means of the dried blood spot (DBS) sampling method. Patients will be asked to to complete a patient diary collecting data on the exact time of intake of nilotinib, exact time of blood sampling, consumption of food and side effects. Patients will be asked to fill out questions about quality of life. Overall study duration for the individual patient is 2 weeks.

Study objective

As food increases nilotinib bioavailability, intake of nilotinib with medium fat Dutch food is expected to increase the bioavailability to an extent that it will allow a reduction of the daily dose by about 30 percent. This both reduces costs substantially and allows for increased adherence to nilotinib simultaneously.

Study design

1. Bloodsampling
On day 1 and 3 of the four day period of fasted intake and on day 4 and 7 of the seven day period of fed intake: blood sampling at 1, 2, 3, 4, 6, 9 and 12 hrs after nilotinib intake in the morning, and 1, 2, 3 and 4 hrs after nilotinib intake in the evening and before the nilotinib intake of the next morning.
On day 1 of the seven day period of fed intake: blood sampling at 1, 2 and 3 hrs after nilotinib intake.
2. Questionnaire

At baseline and after the seven day period of fed intake.
3. Patient diary
On day 1 and 3 of the four day period of fasted intake and on day 1-7 of the seven day period of fed intake.

Intervention

Nilotinib at a lowered dose of 200 mg bid, administered with a meal for a period of seven days.
The half-life of nilotinib is 17 hrs, which suggests that variability in pharmacokinetics, due to variability in the composition of meals, is limited. However, for safety reasons and to get insight into the effect of a high fat meal, patients will be asked to take nilotinib once with a high fat meal, to be planned at day seven (evening intake) of the seven day period of fed intake. A dietician will assist patients to select meals that fit into these guidelines.

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female patients at least 18 years of age;

- Chronic Myeloid Leukemia in chronic phase;
- Currently treated with nilotinib at 300 mg bid for at least 3 months;
- Stable clinical status;
- Written informed consent.

Exclusion criteria

- Patient is unable to fill out a patient diary;
- Patient has insufficient knowledge of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2015
Enrollment:	20
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42074
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4898
NTR-old	NTR5000
CCMO	NL50637.029.15
OMON	NL-OMON42074

Study results