Effect of food on the pharmacokinetics of nilotinib in chronic myeloid leukemia: assessment of a tailored dose reduction (NiFo-study)

Published: 01-04-2015
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To evaluate the effect of real-life food consumption on the pharmacokinetics of nilotinib in CML patients

Ethical review	Approved WMO
Status	Completed
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON42074

Source
ToetsingOnline

Brief title
NiFo-study

Condition

- Leukaemias
- Leukaemias

Synonym
Chronic Myeloid Leukemia; Cancer of white blood cells.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Chronic Myeloid Leukemia, Food, Nilotinib, Pharmacokinetics

Outcome measures

Primary outcome

The difference in pharmacokinetic parameters AUC, Cmax, and Cmin between fasted

and fed administration of nilotinib

Secondary outcome

Inter- and intrapatient variability, patient reported side effects and quality

of life

Study description

Background summary

Chronic myeloid leukemia (CML) is a rare disease, but prevalence is rising due to the effectiveness of treatment with tyrosine kinase inhibitors (TKI) like nilotinib. The acquisition price of nilotinib (600 mg) is ¤103 per day (¤37.600 per year). The complexity of its dosing regimen (twice daily, fasted, approximately 12 hours apart) is a factor substantially contributing to non-adherence, which is directly linked to therapeutic failure. 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 simultaneously.

Study objective

To evaluate the effect of real-life food consumption on the pharmacokinetics of nilotinib in CML patients

Study design

An intervention study with a pre-test post-test design, in patients with

chronic phase CML using nilotinib at a dose of 300 mg bid

Intervention

Nilotinib at a lowered dose of 200 mg bid, administered with a meal for a period of seven days. Patients will be instructed about their meals.

Study burden and risks

Nilotinib concentrations will be measured by means of the DBS sampling method. Sampling will take place on day 1 and 4 during the fasting phase and day 1, 4 and 7 during the non-fasting phase. Patients are asked 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. The health status of patients will be determined prior to study entry from medical history and electrocardiograms. Online Holter monitoring with emphasis on conduction times will be performed in all patients.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or female patients * 18 years of age
2. Chronic myeloïd leukemia in chronic phase
3. Currently treated with nilotinib at 300 mg bid for at least 3 months
4. Stable clinical status
5. Written informed consent

Exclusion criteria

1. Patient is unable to fill out a patient diary
2. Patient has insufficient Dutch language skills

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-12-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tasigna
Generic name:	nilotinib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23914
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
EudraCT	EUCTR2015-000913-36-NL
CCMO	NL50637.029.15
OMON	NL-OMON23914

Study results

Date completed: 09-08-2017

Summary results
Trial ended prematurely