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

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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...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23914

**Bron**
Nationaal Trial Register

**Verkorte titel**
NiFo-study

**Aandoening**

Chronic Myeloid Leukemia
Nilotinib

### Ondersteuning

**Primaire sponsor:** VU University Medical Center
**Overige ondersteuning:** ZonMw

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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.

**Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-03-2015 |
| Aantal proefpersonen: | 20 |
| Type: | Werkelijke startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42074
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten