Validation of dried blood spot sampling in therapeutic drug monitoring of nilotinib

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Primary objective: To develop and validate a DBS sampling method of nilotinib for TDM purposes. Secondary objectives: To get insight into normal trough plasma levels and the use of the DBSM.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON37855

Source
ToetsingOnline

Brief title
Dried Blood Spot Nilotinib

Condition

- Leukaemias

Synonym
Chronic Myelogenous 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: Ministerie van OC&W

Intervention

Keyword: Dried Blood Spot Testing, Drug Monitoring, Finger prick, Nilotinib

Outcome measures

Primary outcome

Difference between specimens across blood sampling methods, and between

duplicate specimens for the same blood sampling method will be determined.

Secondary outcome

NA

Study description

Background summary

The antitumor drug nilotinib has a large inter- and intra individual variability of pharmacokinetics. Also adherence can substantially influence plasma levels. Therapeutic drug monitoring (TDM) of nilotinib is not regularly performed but could be useful to assess that sufficient plasma levels are obtained. Plasma concentrations are usually obtained by venous sampling by medical personel. Dried blood spot sampling (DBSM) could be a useful alternative sampling method.

Study objective

Primary objective: To develop and validate a DBS sampling method of nilotinib for TDM purposes. Secondary objectives: To get insight into normal trough plasma levels and the use of the DBSM.

Study design

The study is designed cross sectional observational in two centers. Venous and finger prick blood samples will be collected simultaneously. With DBSM, capillary blood is obtained from a finger prick with an automatic lancet by the patients themselves and the drop of blood is applied to sampling paper. DBSM is compared with routine assays in venous blood.

Study burden and risks

Patients are asked once for a blood sample by means of a finger prick, and one venous blood sample simultaneously taken with the regular blood collection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with CML who are treated with nilotinib.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	10-12-2012
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL40127.029.12