A non-randomized, open-label study to characterize the pharmacokinetcs of Glivec/Gleevec (imatinib mesylate) in pediatric (age range 1 to less than 4 years) patients with chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) or other Glivec/Gleevec® indicated hematological disorders.

Published: 09-09-2010
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Primary: To characterize the pharmacokinetics of imatinib in pediatric patients age 1 to less than 4 years via appropriate integrated PBPK and pop PK approaches

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

Summary

ID

NL-OMON34200

Source
ToetsingOnline

Brief title
CSTI571A2110

Condition

- Leukaemias

Synonym
Chronic Myeloid Leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: CML, Imatinib, Ph+ ALL, Pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetic data:

* CL/F

* V/F

* Tmax

* PBPK parameters

* Cmax

* AUC

Secondary outcome

Safety and tolerability of imatinib during the study period (including

recording of adverse events and serious adverse events, monitoring hematology

and blood chemistry, measurement of vital signs and performance of physical

examinations, documentation of concomitant medication and therapies).

Study description

Background summary

Currently, there is very limited experience with the treatment of children below 2 years of age and only limited experience treating children younger than 4 years of age with imatinib. The data from this study will help to expand the imatinib PBPK and pop PK model in children in the age range from 1 to less than 4, as well as to help develop appropriate and accurate imatinib dosing regimens.

Study objective

Primary: To characterize the pharmacokinetics of imatinib in pediatric patients age 1 to less than 4 years via appropriate integrated PBPK and pop PK approaches

Study design

Non-randomized, open-label study.

Intervention

Imatinib mesylate (Gleevec/Glivec) at daily dose 260 mg/m2 to 340 mg/m2.

Study burden and risks

Imatinib can have the following side-effects:
Swelling (fluid retention), nausea, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, headache, join pain, abdominal pain, inflammation of the nasal cavity and pharynx, hemorrhage, muscle pain, vomiting, indigestion, cough, pain of the pharynx and larynx, upper respiratory tract infection, dizziness, fever, increased weight, insomnia, depression, influenza and constipation.

There is a risk of skin irritation, bleeding, bruising, pain or infection at the site where blood will be drawn.

Contacts

Public
Novartis

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Patients must be 1 to less than 4 years of age at study entry.
2. Written informed consent must be signed by the patient*s parent or legal guardian.
3. Patients must have the diagnosis of CML or Ph+ ALL or other imatinib indicated hematological disorders.
4. Lansky score must be >= 50
5. Patient must have adequate end organ function as defined by
• Total bilirubin < 1.5 x ULN
• SGPT (ALT) and SGOT (AST) < 2.5 x UNL
• Creatinine < 1.5 x ULN

Exclusion criteria

1. Patients who have received drugs a) known to be metabolized by CYP3A4 or 3A5, b) are CYP inhibitors and inducers, within 2 weeks prior to Visit 2 (except for imatinib)
2. Patients who previously received radiotherapy to >= 25% of the bone marrow, with the exception of patients who received total body radiation as part of a preparatory regimen for hematopoetic stem cell transplant (HSCT)
3. Patients receiving antibacterial and antipyretic medication to treat active infection
4. Patients with International normalized ratio (INR) or partial thromboplastin time (PTT) > 1.5 x ULN, with the exception of patients on treatment with oral anticoagulants
5. Patients whose parents or legal guardian, in the opinion of the investigator, are unlikely to comply with the protocol or safety monitoring requirements

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Glivec
Generic name:	Imatinib mesylate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-09-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2010-018418-53-NL
ClinicalTrials.gov	NCT01066468
CCMO	NL33071.078.10