Distribution NIlotinib in semen in men treated for chronic Myeloid leukAemia

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26150

Source
Nationaal Trial Register

Brief title
DANIMA

Health condition

CML

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Percentage of nilotinib present in seminal fluid in relation to the plasma concentration.

Secondary outcome

Calculated maximal concentration nilotinib absorbed by the partner, using the volume of

distribution of the tyrosine kinase inhibitors and the percentage in seminal fluid found in this study.

Study description

Background summary

CML requires life-long treatment with nilotinib in most patients. As at least 25% of patients is below 40 years and life expectancy seems normal in well responding patients, sexualrelated issues are of major importance. Currently, use of condoms is advised for any male patient, in order to protect their sexual partners against TKI exposure. If this study shows very low and acceptable TKI levels in seminal fluid, condoms may no longer be required in cases where contraception is not needed.

The patients burden consists of two extra blood samples by Dried Blood Spot (DBS) and the effort of collecting and delivery of seminal fluid at two different time points. Patients may feel embarrassment with participation in the study.

Study objective

To determine the level of nilotinib detectable in seminal fluid of men treated with this tyrosine kinase inhibitor And to form an advise if condoms are necessary to protect their sexual partners from exposure to nilotinib.

Study design

2 measure moments with 1 month in between

Intervention

Males have to collect seminal fluid at two different time points with 1 month between collection points. Blood samples will be drawn at the same intervals, within one hour of collection of semen sample.

Contacts

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Eligibility criteria

Inclusion criteria

• male patients

• aged >18 years

• use of nilotinib for a minimal period of 1 month in chronic phase of CML

• willing and capable of donating a semen sample for pharmacological analysis

Exclusion criteria

• Refractory CML with persistent leucocytosis

• Sterilisation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-12-2017
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion Date:	27-11-2017
Application type:	First submission

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
NTR-new	NL6652
NTR-old	NTR6886
Other	METc (VUmc) : 2017.130

Study results