Therapeutic drug monitoring for oral anti-cancer drugs

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21747

Source
NTR

Brief title
M17TDM

Health condition

Tyrosine kinase inhibitors
Oral anti-cancer drugs
Therapeutic drug monitoring

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
Source(s) of monetary or material Support: Roche, Novartis, Pfizer

Intervention

Outcome measures

Primary outcome

To halve the proportion of patients with a drug exposure below TDM target level (historical case comparison) at the third moment of measuring after start of treatment (so after two moments of potential dose adjustment), for most compounds this will be after 12 weeks,

except for compounds with intermittent dosing or a long half-life (see Appendix V of the full protocol for details on PK sampling per compound).

Secondary outcome

Per drug:

- To determine the safety and feasibility of PK guided dosing;

- To determine the objective response rate (according to RECIST 1.1);

- To determine the time to tumor progression and progression free survival;

- To determine the proportion of patients with a drug exposure below TDM target level at the second moment of measuring (so after one moment of potential dose adjustment).

All patients:

- To have a physician adherence of >90% in following the provided patient tailored treatment recommendations which are based on the structured TDM program

Study description

Background summary

Therapeutic drug monitoring for oral anti-cancer drugs. In this study we measure drug levels of oral anti-cancer drugs 4, 8 and 12 weeks after treatment initiation and every 12 weeks thereafter. If the trough level of the drug is below the predefined target level of that drug and the patient does not show any treatment related ¡Ý grade 3 toxicity, the daily dose of the drug will be increased with one dose level or the advice can be given to take the drug concomitant with food.

Study objective

The aim of this study is to show whether TDM leads to a lower proportion of patients with drug levels below the predefined TDM targets after 12 weeks

Study design

NA

Intervention

Doses will be increased in case of drug levels below the predefined TDM target and acceptable toxicity

Contacts

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Eligibility criteria

Inclusion criteria

1. Indication to start treatment with anti-cancer drug from list (see section with list of participating drugs);

2. Age ¡Ý 18 years;

3. Able and willing to give written informed consent;

4. WHO performance status of 0, 1 or 2;

5. Able and willing to undergo blood sampling for PK analysis;

6. Life expectancy ¡Ý 3 months, allowing adequate follow up of toxicity evaluation and antitumor activity.

Exclusion criteria

1. Woman who are pregnant or breast feeding;

2. Unreliable contraceptive methods;

3. Patients with known alcoholism, drug addiction and/or psychiatric of physiological condition which in the opinion of the investigator would impair treatment compliance;

4. Evidence of any other disease, neurological or metabolic dysfunction, physical examination finding or laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of the drug or puts the patient at high risk for treatment-related complications;

5. Legal incapacity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL6695
NTR-old	NTR6866
Other	(NKI-AVL study code) : M17TDM

Study results