Clinical evaluation of dried blood spots for the determination of ribociclib blood levels

No registrations found.

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

Summary

ID

NL-OMON25336

Source
Nationaal Trial Register

Brief title
RIBO-DBS trial

Health condition

Advanced breast cancer

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The main study parameter is the agreement between ribociclib plasma levels of blood collected by venipuncture or DBS.

Secondary outcome

N.A.

Study description

Background summary

Combination treatment with the selective inhibitor of cyclin-dependent kinases 4/6 ribociclib with letrozole significantly improved progression-free survival versus letrozole alone in patients with hormone positive advanced breast cancer.1 Ribociclib is used at a fixed oral dose of 600 mg once daily (3 weeks on / 1 week off), which may be reduced in case of toxicity.

Therapeutic drug monitoring (TDM) is the measurement of drug concentrations in biological fluids to individualize drug dosing. The goal of TDM is to prevent drug failure by achieving adequate drug levels while also reducing toxicity by preventing overexposure.

Dried blood spot (DBS) sampling by finger prick for the use of TDM has become more common over the years, including in the field of medical oncology. Briefly, in order to obtain a DBS, the patient pricks his finger with a lancer and collects a drop of blood on a specific card. Then, DBS have to be dried at ambient temperature and shipped to the laboratory for analysis. For drug concentration assessments, several advantages are presented with the DBS method. In contrast to common venipuncture, DBS sampling is minimal invasive, less painful, and smaller amounts of blood are drawn. Moreover, DBS enables patients to sample the analytical specimen at home at any required time. This is especially beneficial for TDM, because it simplifies sampling at trough level.

A challenge for the validation of a DBS analytical assay is the influence of hematocrit (Hct). Hct affects spot formation, homogeneity and size, drying time, recovery of the analyte, as well as robustness and reproducibility of the assays. Therefore, it is important to investigate the influence of Hct.

The objective of this study is to develop and analytically validate a DBS sampling method for ribociclib using LC-MS/MS. This method is planned to support ongoing and future clinical trials to optimize the treatment of patients with ribociclib.

Study objective

The main study parameter is the agreement between ribociclib plasma levels of blood collected by venipuncture or DBS.

Study design

2020

Intervention

Patients are treated with ribociclib on a dose according to the prescription of the physician. A DBS sample will be obtained simultaneously with a regular plasma sample on a maximum of 4 different regular hospital visits.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 years;
2. Able to understand the written information and able to give informed consent;
3. Treated with ribociclib;
4. Able and willing to undergo a finger prick for dried blood spot sampling.

Exclusion criteria

1. Unable to draw blood for study purposes.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-11-2019
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	NL8197
Other	METC Erasmus MC : METC 19-0467

Study results