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

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The clinical validation of a DBS method for the quantification of ribociclib using liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON48374

Source
ToetsingOnline

Brief title
RIBO-DBS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Borstkanker

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Erasmus MC,Novartis

Intervention

Keyword: Dried Blood Spot, Ribociclib, Validation

Outcome measures

Primary outcome

To develop and validate a dried blood spot (DBS) method for determination of

ribociclib.

Secondary outcome

To characterize the pharmacokinetics of ribociclib.

Study description

Background summary

TDM is the measurement of drug concentrations in blood to determine pharmacokinetic parameters, in order to optimize individual dosage regimes. Dried Blood Spot (DBS) sampling by finger prick for the use of TDM has become more common over the years, including the field of medical oncology. DBS sampling is minimally invasive and is a promising patient-friendly alternative to venous sampling, since the technique can be performed by patients at their homes and the samples can be sent to a laboratory by regular mail for analysis. Ribociclib is a selective inhibitor of cyclin-dependent kinases 4/6 and results in combination with letrozole in improved progression-free survival versus letrozole alone in patients with hormone positive advanced breast cancer. 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. Currently we are exploring the need for dose individualization based on therapeutic drug monitoring as part of nationwide SONIA trial (NL62197.031.17). When a DBS method is validated successfully, we will be able to monitor the ribociclib concentration less invasively at an optimally timed time-point. Therefore, the objective of this study is the development and analytically validate a DBS method for ribociclib.

Study objective

The clinical validation of a DBS method for the quantification of ribociclib using liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Study design

Cross-sectional observational study.

Study burden and risks

Participants will undergo at a maximum of four hospital visits a finger prick (<50 uL) and a 4.5 mL blood sample taken by a venipuncture. These interventions may cause mild pain or local irritation. All samples will be taken during regular hospital visits. Blood samples will be taken during standard blood control to minimize the number of venipunctures.

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

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

Unable to draw blood for study purposes.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

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

Ethics review

Approved WMO

Date:	26-09-2019
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
CCMO	NL70792.078.19