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

Gepubliceerd: 25-11-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25336

Bron
Nationaal Trial Register

Verkorte titel
RIBO-DBS trial

Aandoening

Advanced breast cancer

Ondersteuning

Primaire sponsor: Novartis
Overige ondersteuning: Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the agreement between ribociclib plasma levels of blood

collected by venipuncture or DBS.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

2020

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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06-18197784

Wetenschappelijk

Erasmus MC Cancer Institute
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unable to draw blood for study purposes.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8197
Ander register	METC Erasmus MC : METC 19-0467

Resultaten