A rapid DNA-test for early detection of bloodstream infections in intestinal failure patients

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We hypothesize that the ddPCR has a sensitivity of at least 80%

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

Samenvatting

ID

NL-OMON23613

Bron
Nationaal Trial Register

Aandoening

Intestinal failure

Ondersteuning

Primaire sponsor: MLDS
Overige ondersteuning: MLDS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is the sensitivity of the ddPCR to detect pathogens in blood compared with the gold standard.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: To compare the diagnostic accuracy of the droplet digital PCR (ddPCR) with the gold standard (blood cultures with clinical data) for rapid detection of bloodstream infections in intestinal failure (IF) patients.
Background: IF patients depend on life-long home parenteral nutrition, a complex treatment that centers on management of their central venous catheter to prevent the most daunting complication: catheter-related bloodstream infection. Use of molecular techniques holds promise to improve and speed up bloodstream infection diagnostics as compared to the traditional culturing of pathogens, since several assays have become available for rapid detection of pathogens in whole blood. Howerver, most molecular techniques have a moderate sensitivity which severely limits its use in a clinical setting. The ddPCR is a culture-independent molecular test that has been developed to improve sensitivity of pathogen detection in whole-blood.
Methods: This study concerns a prospective two-year single-blind cohort study. IF patients presenting to the Radboudumc with a suspected diagnosis of bloodstream infection will be included. First, blood cultures will be collected according to current standard care procedures. Next, two sets of 5 mL blood samples will be collected (no additional punctures needed) for ddPCR analyses. Two blinded research analysts will analyze the samples. After adequate treatment, patients will be followed for three months. Primary outcome is the sensitivity of the ddPCR to detect pathogens in blood compared with the gold standard. Secondary outcomes include test characteristics (e.g. specificity), diagnostic accuracy of ddPCR in patients who received antibiotics within 3 and 7 days before presentation, and for detecting Gram-positive/Gram–negative bacteria and fungi.

Doel van het onderzoek

We hypothesize that the ddPCR has a sensitivity of at least 80%

Onderzoeksopzet

T0: Presentation at the emergency department. Bloodsamples will be collected directly after collection of bloodcultures.
T3: The end of 3 months of follow up

Onderzoeksproduct en/of interventie

Directly after collection of the first sets of blood cultures, two EDTA blood samples of 5 mL will be collected from the CVC and two 5 mL EDTA blood samples will be collected from the peripheral veins, where the blood cultures were previously drawn.

Contactpersonen

Publiek

Radboud umc
Veerle Gillis

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Wetenschappelijk

Radboud umc
Veerle Gillis

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Clinical suspicion of a bloodstream infection.
• Written informed consent before entering study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Intestinal failure patients <18 years of age.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-05-2019
Aantal proefpersonen:	125
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:	07-05-2019
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	NL7716
Ander register	Commissie mensgebonden onderzoek Arnhem Nijmegen en CMO Radboudumc : 2019-5342

Resultaten