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

No registrations found.

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

Summary

ID

NL-OMON23613

Source
Nationaal Trial Register

Health condition

Intestinal failure

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• Specificity of ddRST.

• Positive/negative predictive values of ddRST
• Positive/negative likelihood ratios of ddRST.
• Sensitivity/specificity of ddRST:
o in patients who received antibiotics ≤3 days before presentation.
o in patients who received antibiotics ≤7 days before presentation.
o for detecting Gram-positive bacteria.
o for detecting Gram-negative bacteria.
o for detecting fungi.
o in relation to sepsis severity (sepsis versus septic shock)
o compared to follow-up bloodcultes

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

• Intestinal failure patients <18 years of age.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2019
Enrollment:	125
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-05-2019
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	NL7716
Other	Commissie mensgebonden onderzoek Arnhem Nijmegen en CMO Radboudumc : 2019-5342

Study results