16S PCR in patients with an infected vascular graft, mycotic aneurysm or a non-infected aortic aneurysm

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The aim of this study is to compare the 16S PCR technique with standard bacterial cultures of infected vascular grafts, mycotic aneurysms and non-infected aortic aneurysms.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON37045

Source
ToetsingOnline

Brief title
16S PCR in patients with arterial or vascular prosthesis infections.

Condition

- Vascular disorders NEC

Synonym
1. Infected vascular graft or arterial wall 2. Infected vascular prosthesis or bloed vessel wall

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Culture, Infection, PCR, Vascular prosthesis

Outcome measures

Primary outcome

Sensitivity and specificity of the 16S PCR test. The standard bacterial culture

is the reference standard.

Secondary outcome

Not applicable

Study description

Background summary

A vascular prosthesis infection is a rare, but very serious complication. This complication implies an extensive reoperation with explantation of the graft and revision wit an autologous (venous) graft. This therapy requires major surgery and is associated with 15% mortality, even in experienced hands. Postoperatively, patients are treated with antibiotics for at least 6 weeks. A primary infection of an artery, often presenting as a mycotic aneurysm, is treated rather similarly. The infected arterial wall will be excised completely, followed by a reconstruction using antilogous vein or an antibiotic-impregnated vascular prosthesis. In these patients additional treatment with 6 weeks of antibiotic therapy postoperatively is indicated too. Long-term antibiotic therapy is intended to prevent recurrent vascular prosthesis infection or a potentially lethal septic bleeding from a venous graft. The type of antibiotic therapy for patients with an infected arterial wall or vascular prosthesis is determined by the type of bacterium causing the infection. Therefore, identification of bacteria from the infected arterial wall or vascular prosthesis is important and typing of a bacterium is obtained by means of microbacterial cultures. The sensitivity for this test in these patients may be limited and in 25% of patients no bacteria will be demonstrated. There is a need for a better test to demonstrate the presence of bacteria in the arterial wall and vascular prostheses. Molecular techniques to demonstrate the presence of bacteria may have additional diagnostic value in these patients.

16S PCR

The 16S PCR is a molecular technique to demonstrate and identify bacteria. The 16S rRNA gene is necessary to bacterial protein synthesis and is present in all bacteria. Using specific parts of the 16S rRNA gene most culturable and non-culturable bacteria can be identified. Using 16S PCR the bacterial 16S rRNA base sequence can be determined. The bacterial identity is then determined by comparing the base sequence with the sequences of already identified bacteria. The 16Spatch database, for example, contains the sequences of more than 1.000 unique bacteria.

Bacteria in the arterial wall

Since 1999 the 16S PCR technique has been used in multiple publications to demonstrate the presence of bacteria atherosclerotic plaques. This technique has always been used in research projects studying the pathogenesis of atherosclerosis. However, prior to the use of 16S PCR, it has been known that bacteria may be present in atherosclerotic arteries of patient without symptoms of a bacterial infection. In a series of 176 patients, who underwent open aortic aneurysm repair using a vascular prosthesis, positive mural thrombus cultures were observed in 14% of patients. During follow up however, no graft infections were registered. In another series of 500 patients undergoing aortic aneurysm repair bacteria in the arterial wall were demonstrated in as many as 185 patients (37%). One patient developed a prosthetic graft infection after 6 years caused by a bacterium other than the one found during the initial operation. The authors therefore conclude, that routinely culturing asymptomatic, non-ruptured aneurysms is not indicated, since a positive culture has no consequences.

Study objective

The aim of this study is to compare the 16S PCR technique with standard bacterial cultures of infected vascular grafts, mycotic aneurysms and non-infected aortic aneurysms.

Study design

Pilot study. In all patient undergoing surgery for an infected vascular graft, mycotic aneurysm or non-infected aortic aneurysm tissue will be obtained to be analysed by standard bacterial cultures and the 16S PCR test. If pus is found, this will be analysed too. De 16S PCR results will be compared with the standard bacterial cultures. The patients with non-infected aortic aneurysms with negative bacterial cultures will be considered negative controles.

Study burden and risks

No burden and minimal risk.

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

- Patients scheduled for explantation of an infected vascular graft
- Patients scheduled for open repair of a mycotic aneurysm
- Patients scheduled for open repair of a non-infected aortic aneurysm

Exclusion criteria

- Endovascular repair. Since a tissue sample is not possible in these patients.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2012
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL42409.101.12