Cell-free DNA as a new, minimally invasive and sensitive biomarker for early detection of allograft rejection after heart transplantation

Published: 08-09-2017
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Our pilot study is designed to obtain data on sensitivity of g-cfDNA with the ddPCR technique to diagnose tissue rejection in heart transplant recipients, as determined by the golden standard EMB.

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON45738

Source
ToetsingOnline

Brief title
cfDNA for detection of heart transplant rejection

Condition

- Heart failures

Synonym
cardiac surgery, heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: cell-free, DNA, heart transplantion, rejection

Outcome measures

Primary outcome

Sensitivity: percentage of patients positive for rejection according to the

golden standard EMB that are also positive according to the ddPCR technique.

Secondary outcome

Not applicable.

Study description

Background summary

For heart transplantations acute rejections still occur at 15-30%. The golden standard to diagnose is by collection of endomyocardial biopsies (EMBs) and histologically evaluation for signs of rejection. These biopsies are performed 15 times a year per patient and consist of 5 heart tissue samples, thus adding up to 75 tissue biopsies. This procedure is costly, highly inconvenient for the patient and has the danger of complications (tricuspid valve damage, cardiac tamponade, coronary fistula, rhythm disorders).No other diagnostic tool is available to heart transplant rejection.

Study objective

Our pilot study is designed to obtain data on sensitivity of g-cfDNA with the ddPCR technique to diagnose tissue rejection in heart transplant recipients, as determined by the golden standard EMB.

Study design

Explorative prospective single center study

Study burden and risks

In our opionion there are no risks associated with participation in this study.

The additional vial of blood is drawn from a temporary sheet, which is already required for EMB. Therefore no extra puncture is necessary for this study. The hope is that in the future we can use g-cfDNA to reduce the amount of EMB. The data will be prospectively collected and compared with the histological results from the EMB. Standard of care will be based on the EMB and not influenced by the outcome of the g-cfDNA.

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

Adult (*18 years) heart transplant patients

Exclusion criteria

No written informed consent

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:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-09-2017
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	NL60254.078.17