Cardiovascular function after Stem cell Transplantation

Published: 24-03-2014
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To study whether CMR analysisdifferences in aortic stiffness and myocardial lipid accumulation between SCT recipients and healthy, age-matched controls

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON41232

Source
ToetsingOnline

Brief title
The CAST-study

Condition

- Leukaemias
- Cardiac disorders, signs and symptoms NEC

Synonym
aortic dysfunction, aortic stiffness

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Maarten Kappelle Stichting

Intervention

Keyword: Cardiovascular function, Children, Magnetic resonance imaging, Stem cell transplantation

Outcome measures

Primary outcome

Distensibility and pulse wave velocity after SCT, as assessed by CMR.

.

Secondary outcome

Secondary study parameters/endpoints: Echocardiographic and CMR parameters of

cardiac function, including ejection fraction, global myocardial strain,

myocardial fibrosis and myocardial lipid accumulation after SCT.

Study description

Background summary

Rationale: The disease-free survival in children undergoing stem cell transplantation (SCT) for both malignant and non-malignant diseases has significantly increased during last decades. Therefore, treatment-related morbidity and long term health issues have become increasingly important as a measurement of overall treatment outcome. Cardiovascular pathology is a recognized side effect of treatment. In current practice, monitoring of cardiovascular function is restricted to echocardiographic analysis, and no specific attention is given to vascular wall integrity. CMR is a more sensitive technology to accurately assess ventricular function and aortic stiffness. Aortic stiffness, measured by CMR, is a known predictive marker for overall vascular integrity and atherosclerosis. In this (pilot)study, we will us CMR to investigate both ventricular function and aortic stiffness in children undergoing SCT.

Study objective

To study whether CMR analysisdifferences in aortic stiffness and myocardial lipid accumulation between SCT recipients and healthy, age-matched controls

Study design

prospective observational

Study burden and risks

The burden consists of 1 CMR investigation of one hour, without administration of contrast agent. In preparation for CMR, 6 hours fasting is required (for adequate quantification of myocardial lipid accumulation). Prior to CMR, participants will have the possibility to first experience CMR in a dummy-MRI setting.
The possible direct benefit may involve more accurate information on the ventricular function (compared to routine echocardiography. Furthermore, follow-up schemes may be altered based on the findings of possible aortic dysfunction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients 16-25 yrs of age after a stem cell transplantation < 16yoa
No mental retardation
No contra-indication for MRI examination: pacemaker dependency, claustrofobia.
healthy subjects: based on medical history and physical examination. Drug/medication use.

Exclusion criteria

< 16yrs of age
Mental retardation, Contra-indications for MRI-examination

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	24-03-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-07-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-07-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL44973.058.13