Normal values of biventricular function, volumes and mass in a paediatric population assessed by magnetic resonance imaging employing steady-state free precession at 3 Tesla

Published: 22-05-2013
Last updated: 24-04-2024

To obtain normal values of biventricular volumes, ejection fraction and wall mass using MRI SSFP sequences at 3Tesla.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38814

Source
ToetsingOnline

Brief title
Paediatric normal values of 3T cardiac MRI

Condition

- Other condition

Synonym
ejection fraction, ventricular volumes

Health condition

normaal waarden hartgrootte en functie bij kinderen

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: 3T MRI, Children, Ventricular function

Outcome measures

Primary outcome

Left ventricular end-diastolic and end-systolic volume, ejection fraction and

wall mass.

Right ventricular end-diastolic and end-systolic volume, ejection fraction and

wall mass.

Secondary outcome

Intra- and interobserver variability of 3T cardiac MRI in children.

Study description

Background summary

Cardiac MRI using SSFP sequences at 1.5 Tesla is a validated clinical imaging tool. It is routinely used in clinical decision making. New developments in MRI are towards imaging at 3 Tesla. This technique has been validated for cardiovascular imaging in adults and clinical applications in children are increasingly used. There is a lack of normal data that are used as reference in the interpretation in clinical studies in patients with heart disease in the pedaitric age range.

Study objective

To obtain normal values of biventricular volumes, ejection fraction and wall

mass using MRI SSFP sequences at 3Tesla.

Study design

Prospective observational study in healthy children

Study burden and risks

Cardiavascular MRI at 3Tesla according to common clinical protocols will be applied. These sequences have been demonstrated to be safe and are not related to side-effects. Main risk is related to the noise of the scanner during imaging. Noise will be reduced by external protection of the ears. Some subjects may find it difficult to lie still in the scanner for 30-40 minutes. 3T cardiac MRI has been associated with increased risk of tissue heating, considering the higher specific absorption rate compared to 1.5 T cardiac MRI. This risk will be limited by applying clinically accepted and approved imaging parameters. The study needs to be performed in children because we aim to acquire normal values for cardiac size and function in the paediatric age range. These values have been demonstrated to depend on age, gender and body size. The relationsship between cardiac size and these parameters is non-linear. Therefore normal values for the paediatric age range cannot be obtained by extrapolation form adult values.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age 8 - 17 Able to undergo cardiac MRI

Exclusion criteria

Disease affecting the circulatory system Metal implants Unable to follow instructions during cardiac MRI Irregular heart rhythm Claustrophobia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	22-05-2013
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	NL42903.078.12