Neonatal thymectomy; consequences for homeostasis and regulation of the immune system?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON29974

Source ToetsingOnline

Brief title Impact of thymectomy on the immune system

Condition

- Congenital cardiac disorders
- Autoimmune disorders
- Cardiac therapeutic procedures

Synonym congenital heartdisease, transposition of the great arteries

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

1 - Neonatal thymectomy; consequences for homeostasis and regulation of the immune s \dots 5-05-2025

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

Intervention

Keyword: homeostasis, lymphocytes, regulatory T cells, thymectomy

Outcome measures

Primary outcome

- 1) Number of FOXP3+ cells compared to healthy controls
- 2) Ratio naïve T cells : memory T cells
- 3) Proliferate rate of naïve and memory T cell pool

Secondary outcome

1) Incidence of autoimmune diseases, malignancies, infectious diseases

Study description

Background summary

From 1977 onwards more than 100 patients have been admitted to the Wilhelmina Children*s Hospital in Utrecht for surgical correction of a transposition of the great arteries. During this procedure the complete thymus was excised. Little is known about the impact of this procedure on the immune system. Previous studies show that up to ten years after thymectomy no increase in infectious or autoimmune diseases could be observed. New surgical techniques and improved cardiopulmonary bypass systems have resulted in more children being operated at an increasingly younger age. These children should have an extensive follow-up. With innovative research techniques the immune system can be studied accurately resulting in a better understanding of the impact of thymectomy on the developing immune system.

Study objective

This study observes the immune system of children and adults who have been without a thymus for 3 to 30 years. Our objective is to study the role of the thymus in the developing immune system. In addition this study will give insight in the long term effects of neonatal thymectomy.

Study design

Informed consent will be asked of approximately 100 patients. Of these patients one blood sample will be drawn, if possible during a regular OPD check-up (children 3-8 years 18 ml, >8 years 27 ml). The blood samples will be isolated and stored for experiments at a later date. The immune system will be assessed by means of FACS analysis, thymic function by determining TREC content and peripheral tolerance by means of measuring auto-antibodies. These experiments will reveal the role of the thymus in the homeostasis of CD4 and CD8 cells, both naïve and memory populations. The development of "FOXP3+ regulatory T cells" in this setting has our particular interest. In addition to the laboratory results, clinical data will be collected of the participating patients. Following informed consent, the occurrence of autoimmunity, infectious diseases and malignancies will be retrieved from the general practitioner.

Study burden and risks

The nature of this study implies limited burden and negligible risks.

1) Time burden: approximately 45 minutes on one occasion (if possible during an OPD visit)

2) Vena puncture: burden of the puncture, limited risk of bleeding / infection

Contacts

Public

Universitair Medisch Centrum Utrecht

Postbus 85090 3508 AB, Utrecht Nederland **Scientific** Universitair Medisch Centrum Utrecht

Postbus 85090 3508 AB, Utrecht Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

Inclusion criteria

Arterial switch operation in the Wilhelmina Kinderziekenhuis between 1977 and 2003

Exclusion criteria

moved abroad

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-01-2008
Enrollment:	100
Туре:	Actual

Ethics review

Approved WMO	
Date:	02-01-2007
Application type:	First submission
Review commission:	METC NedMec

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 CCMO ID NL12421.041.06