Translational research to study the effect and mechanism of microbiota in paediatric immune-mediated diseases.

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In vitro selection of microbiota that can be used in a subsequent trial with children with IMD. The selection will be made based on the cytokine profile and immune cell characterization after co-culture of PBMC*s with bacteria. Influence of human...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30483

Source
ToetsingOnline

Brief title
Translational studies with microbiota

Condition

- Immune disorders NEC

Synonym
immune-mediated diseases / disturbed immune system diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Er is een subsidie-aanvraag ingediend bij Senter voor een project waar voorliggend onderzoek deel één en twee is. Een kopie van deze

aanvraag treft u als bijlage aan. Zie verder sectie J.,VSM

Intervention

Keyword: Cytokine profile, Immune cell characterization, Microbiota, Paediatric immune-mediated diseases

Outcome measures

Primary outcome

Cytokine production profile and character of immune cells of childeren with IMD

exposed to several species of microbiota in vitro and in a trans-well system

with humane intestinal epithelial cells.

Secondary outcome

None

Study description

Background summary

According to the hygiene hypothesis, the increase in immune-mediated diseases (IMD) during the last decades may be due to decreased contact with (parts of) microbiota in early life. This contact may be necessary for a normal and balanced development of the immune system. Therefore, along these lines, immune mediated diseases may be prevented or treated by the administration of (parts of) microbes. Recently we have selected three probiotics species by in vitro exposing peripheral blood mononuclear cells (PBMC*s) to several microbiota that had been shown in previous research to be able to pass the stomach and to adhere to intestinal epithelium. Subsequently, we administered this particular combination of microbiota to pregnant allergic women during the last 6 weeks of pregnancy and to their high-risk offspring during the first 12 months of life. This resulted in a lower prevalence of eczema at the age of 3 months (OR 0.3, 95%CI=0.2-0.9). These preliminary results made us continue research in this field. Next to allergies, Juvenile Chronic Arthritis (JCA), Diabetes Mellitus type I (IDDM), Atopic Dermatitis (AD) and Crohn*s disease (=CD; together with Ulcerative Colitis representing Inflammatory Bowel Disease=IBD) are all prevalent diseases, mediated by the immune system. In this project we will select probiotic species by in vitro exposing PBMC*s of children with the diseases mentioned, to several microbiota and measure the production of

cytokines by PBMC's as well as determining the phenotype of PBMC's. PBMC*s will subsequently be exposed to the selected bacteria in a trans-well system with human gut epithelial cells to confirm the data. PBMC's will be added to the basolateral compartment, while probiotics are added apically of the cell line Caco-2.

Study objective

In vitro selection of microbiota that can be used in a subsequent trial with children with IMD. The selection will be made based on the cytokine profile and immune cell characterization after co-culture of PBMC*s with bacteria. Influence of human gut epithelial cells will be studied in a trans-well system.

Study design

In vitro study with PBMC's isolated from blood obtained from children with IMD.

Study burden and risks

Risks and burden for subjects are considered minimal. Subjects will be invited for the subsequent interventional study with selected probiotic bacteria if they wish. Blood will be withdrawn simultaneous with routine withdrawal as much as possible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Child
Diagnosed IMD (JCA, IDDM, AD or CD) according to international accepted standards.

Exclusion criteria

Diseases of the blood or bloodforming organs or the immune system.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-07-2007
Application type:	Amendment

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	NL15227.041.06