

Study of gut microbiota profile in children with propionic acidemia

Published: 25-11-2016

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NA

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Inborn errors of metabolism
Study type	Observational non invasive

Summary

ID

NL-OMON21010

Source

NTR

Brief title

PAMDC

Condition

- Inborn errors of metabolism

Health condition

Propionic acidemia

Research involving

Human

Sponsors and support

Primary sponsor: Danone Nutricia Research

Source(s) of monetary or material Support: Material support provided by Nutricia Research

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Phylogenetic composition of the gut microbiota in PA patients

Secondary outcome

NA

Study description

Background summary

NA

Study objective

NA

Study design

Routine hospital visit (T0), First stool collection (week1), Second stool collection (week 5), third stool collection (week 9), fourth stool collection (week 13)

Intervention

NA

Contacts

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Eligibility criteria

Age

Children (2-11 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Having PA (or having a sibling with PA) and age >4 yr and preferably <10 yr (upper age limit is 18 yr).

Exclusion criteria

PA patients with confounding intestinal diseases (e.g. colon rectal cancers, Crohn's disease, Ulcerative colitis).

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 31-01-2017
Enrollment: 40
Type: Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 25-11-2016
Application type: First submission

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
NTR-new	NL6130
NTR-old	NTR6269
Other	: IRAS project ID: 199265

Study results

Summary results

NA