

Biochemical implications of ketogenic diet in children with intractable epilepsy: a metabolimics approach.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON35189

Source

ToetsingOnline

Brief title

Biochemical implications of ketogenic diet in children with epilepsy.

Condition

- Seizures (incl subtypes)

Synonym

convulsions, epilepsy

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Nationaal Epilepsie Fonds

Intervention

Keyword: biochemical, epilepsy, ketogenic diet

Outcome measures

Primary outcome

The act of altering of biochemical processes. Is there a trend? Is there a relation between changes in biochemical processes and a positive or negative effect on the seizures?

Secondary outcome

n.a.

Study description

Background summary

Anti-epileptic drugs are the treatment of first choice in childhood epilepsy. In case of treatment failure, which occurs in 10-20% of the children, there is a need for other treatment options such as the ketogenic diet. Each year, 40-50 children with intractable epilepsy start with the ketogenic diet, which is prescribed in a limited number of centres in the Netherlands. The ketogenic diet consists of high fat and low carbohydrate and protein concentrates. Fat will be the most important energy source instead of carbohydrates. The aim of the diet is to come in ketosis. Ketosis probably plays a role in the reduction of the number of epileptic seizures, but it is still unclear in which way this influences the brain metabolism and how it protects against seizures. At this moment it can not be predicted in which child the ketogenic diet will be effective. This diet has, however, a large impact on daily life of both patient and parents/caretakers because of the radical changes in eating habits.

Study objective

Because the ketogenic diet has a large impact on daily life of both patient and parents/caretakers, it would be a great improvement if one would be able to predict the effectiveness at a much earlier stage. We hope to be able to trace mechanisms by which the ketogenic diet exerts its effects and to find (a) predictive marker(s), in order to predict earlier if the diet will be effective. The study performed in the UMCG will be a pilot study investigating metabolic

changes during the ketogenic diet. In this way, we hope to gain more insight into the effects of the ketogenic diet on metabolic profiles and changes therein and possibly to find (a) prediction marker(s).

Study design

During the treatment with ketogenic diet additional investigations will be performed to better understand the effects of the ketogenic diet on metabolic profiles and changes therein. A number of additional laboratory provisions will be made, both in blood and in urine. Using a glucose sensor meter gives the opportunity to continuously monitor glucose levels during 24 - 48 h. Apart from clinical reasons to monitor glucose levels continuously, it also offers the possibility to examine the possible relationship between glucose level, the degree of ketonemia and the time of taking the meal.

Study burden and risks

The extra investigations will take place during regular visits, so the additional burden is limited. For the regular treatment with ketogenic diet, frequent examinations in blood and urine have to be performed. Our pilot study only needs 3 extra blood drawings, which is acceptable to our opinion. The blood necessary for the remaining investigations will be taken during the same puncture as the regular control. Using a glucose sensor meter, information about the glucose levels can be easily obtained every five minutes through a subcutaneous needle, which can stay in position for 24 to 48 h. As a result, only one puncture is necessary to obtain information over this period, which makes the glucose sensor meter user-friendly.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children treated with ketogenic diet

Exclusion criteria

- Defects in energy metabolism, with particular emphasize on free fatty acids metabolism
- Porphyria
- Long QT syndrome or other cardiac rhythm problems
- Severe chronic disease of liver, kidneys or pancreas
- Noncompliance parent/caretaker/patient or when communicationproblems with parent/caretaker/patient are expected.

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):	27-03-2013
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO	
Date:	13-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37624.042.11