KetoEasy meal plan for Ketogenic Diet Therapy in children 2-12 years with parmacoresistant epilepsy

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Primary Objective: To evaluate whether KDT application as the KetoEasy meal plan induces ketosis and leads to seizure reduction in children 2-12 years with refractory epilepsy.Secondary Objective(s): To evaluate-Feasibility: application in daily…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inborn errors of metabolism
Study type	Interventional

Summary

ID

NL-OMON51530

Source
ToetsingOnline

Brief title
KetoEasy mealplan

Condition

- Inborn errors of metabolism
- Seizures (incl subtypes)

Synonym
pharmacoresistant epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting de Merel

Intervention

Keyword: Children, Epilepsy, KetoEasy, Ketogenic Diet therapy

Outcome measures

Primary outcome

Primary parameter/endpoint

Percentage of included patients having ketone levels > 3 mmol/l within4 months after start Ketogenic Diet Therapy by using the KetoEasy mealplan.

Secondary outcome

Secondary study parameters/endpoints

- Ketone levels (daily measured) during 4 month study period (median/mean and range mmol/l in blood week 1-5, month 2,3,4 and total study period)

- Time to adequate ketosis (in days) after diet initiation

- Number and kind of side effects: hyperketosis (>6.5 mmol/l), hypoglycemia (< 2.5 mmol/l),hyperlipids (cholesterol >5 mmol/l , triglycerides >3 mmol/l), gastro-intestinal problems (constipation, vomiting, diarrhea), food refusal, weight loss (>5% of baseline weight)

-Seizure reduction defined as > 50% seizure reduction 3 months after completing KDT dietinitiation

-Number of drop outs and reason for stopping

-Feasibility of KDT application by the use of the KetoEasy meal plan user-friendliness, variety and application in daily use by parents.

-Nutritional composition of the food intake at baseline, at week 5 and end study (energy, protein, fat and carb)

Other study parameters

-Feasibility of KDT as use of KetoEasy meal plan during initiation, fine tuning

and follow up by the dietitians and medical doctors of the ketoteam.

Study description

Background summary

General
According to RIVM (2015) every year 3.000 children are diagnosed with epilepsy in the Netherlands. Response rates to standard treatment with anti-epileptic drugs are 70% . For the Netherlands this means 2100 (70%) seizures adequately respond to anti-epileptic drugs. However, in 900 (30%) children this is not the case. For this group Ketogenic Diet Therapy (KDT) is an important treatment option.
Ketogenic Diet Therapy (KDT) is a specialist medical diet for children with pharmaco resistant (i.e.2-3 anti-epileptic drugs have failed) epilepsy. It is an extremely high fat (71-90 en%), very low carbohydrate (5-19 en%) diet without caloric restriction and normal protein. This situation mimics the metabolic state of fasting and induces the production of ketone bodies. The reaction of the body is based on the ratio between the ketone producing nutrient (fat) and the non-ketone producing nutrients (carbohydrates plus protein). A 4:1 ratio means 4 grams of fat is used opposite to 1 gram carbohydrates plus protein which is the most strict version and known as the Classic Diet. Lower dietary ratio's as 3:1 are recommended for (young) infants. KDT requires major adjustments of the regular menu and side effects are frequently seen
KDT nowadays is a well-established treatment option in both children and adults with pharmaco resistant epilepsy, in case of severe side effects of AEDs or while waiting for epilepsy surgery. KDT is a treatment option of first choice in case of specific metabolic diseases as Glucose Transporter Deficiency type 1 (GLUT-1), Pyruvate Dehydrogenase Deficiency (PDHC) or mitochondrial diseases. In clinical practice KDT is initiated in a step-wise manner which can be done safe and effective both during a short hospital admission or outpatient . Evaluation of efficacy is done after period of 3 months after dietinitiation is completed. In case the diet is effective it will be maintained for 2 years

The Ketoteam of the Erasmus MC-Sophia Children*s hospital has initiated KDT in >280 children both outpatient as well as inpatient. However, this successful treatment has been hampered by several challenges. From both the parent and team perspective, the application of the KDT is a resource-consuming and time-intensive process.

Moreover, recent research among our parent group shows that calculation, weighing and preparation of the daily ketogenic menu*s and snacks are a significant barrier for them in daily practice. This might not only cause a lot of stress but might also be reason for stopping KDT.
At the Erasmus MC-Sophia children*s hospital both parents and the Ketoteam strongly feel the need to tackle these barriers and make application of KDT less stressful by making it more easy. Therefore, the Ketoteam has developed a simplified version of KDT: the Keto-Easy meal plan. Keto-Easy is a well-structured meal plan that is based on Classic Ketogenic Diet with 3:1 ratio with recipes of the same nutritional composition which makes them interchangeable. The application of KDT by the use of Keto-Easy requires no calculation neither by the parents nor the dietitian.
A delegation of our parent support group has tested a selection of the developed recipes. Their opinion and advices have been very valuable and has contributed to improvement of the meal plan.

Study objective

Primary Objective:
To evaluate whether KDT application as the KetoEasy meal plan induces ketosis and leads to seizure reduction in children 2-12 years with refractory epilepsy.

Secondary Objective(s):
To evaluate
-Feasibility: application in daily practice
-Safety: occurrence of side effects
-Growth : parameters by anthropometrics
-Adherence: number of drop outs and reason for stopping
-Experience in daily practice by parents

Other objective(s)
To evaluate
-Experience in daily practice by parents and the ketoteam

Study design

This is a proof of concept study of 4 months.

Intervention

Ketogenic Diet Therapy (KDT) is a specialist medical diet for children with pharmaco resistant (i.e.2-3 anti-epileptic drugs have failed) epilepsy. It is an extremely high fat (71-90 en%), very low carbohydrate (5-19 en%) diet without caloric restriction and normal proteinIn this study patients eligible for ketogenic diet therapy will follow the Classic version of KDT by the use of the KetoEasy meal plan. The Keto-Easy meal plan requires NO calculation neither

by the parents nor the dietitian.
Keto-Easy is a well-structured meal plan that is based on Classic Ketogenic Diet with 3:1 ratio. This ratio consists of number of grams of ketone producing nutrient (fat) opposite to the number of grams of non-ketone producing nutrients (carbohydrates plus protein). The higher the ratio, the stricter the diet. The KD used in this diet is based on a moderate 3:1 diet ratio.
The Keto Easy meal plan:
- is suitable for children age 2-12 years,
- recipes are based on units (1, 1.5 and 2 units),
- the dietitian determines the units the patient needs to follow to match the individual need,
- the parent follows the recipe by using the amounts of the ingredients noted at the
corresponding unit,
- the recipes have the same nutritional composition which makes them interchangeable,
- the accompanied keto-snacks and sweets are based on ratio 3:1 and 4:1,
- the dietitian is able to fine-tune the diet by the choice of units and ratio of the keto-snacks
and sweets,
- there are > 100 recipes available of several categories that can be used either as main
course or as a snack,
- the recipes contain as less ingredients as possible and are easy to prepare,
- the majority of the recipes can be stored in the freezer,
- a number of recipes are especially designed to be used by the total family (family recipe).
- majority of the recipes is tested by parents of the parent support group of the ketoteam.

The meal plan is available for parents as a word document. Majority of the recipes are illustrated with a photo.

Study burden and risks

The extent of the burden of our study is considered low.The ketogenic diet have been proven feasible and safe in previous studies. Side effects are well described and can be resolved by close monitoring by the experienced multidisciplinary ketoteam. No extra visits or checks are required in this study as the routine of the regular KDT protocol will be followed. Outcomes of this study give an opportunity to tackle barriers and make application of KDT less stressful by making it more easy while using the KetoEasy meal plan. Overall goal is to get this successful treatment more widely available for children in the Netherlands.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-age 2-12 years
-seizures inadequately responding to 2-3 anti-epileptic drugs
-or experiencing severe side effects on anti-epileptic drugs
-or on waiting list for epilepsy surgery
-be able to read Dutch language
-signed informed consent

Exclusion criteria

-complex medical condition requiring hospitalization for ketogenic diet initiation
-age < 1 year or > 12 years

-KDT used in the past

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2022
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-02-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2025
Application type:	Amendment
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	NL80304.078.22