Cost-effectiveness of a ketogenic diet in children with therapy-resistant epilepsy.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19966

Source
Nationaal Trial Register

Brief title
KOEK

Health condition

EN:Epilepsy, Seizures, Intractable, Ketogenic diet, Cost-effectiveness, Economic evaluation

NL:Epilepsie, Aanvallen, Therapie resistent, ketogeen dieet, Kosten-effectiviteit, Economische evaluatie

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. A 50% reduction of the proportion of seizures, timepoint: 16 months;

2. Cost per seizure reduction, timepoint: 16 months;

3. Cost per QALY, timepoint: 16 months.

Secondary outcome

1. Seizure frequency and severity, timepoint:16 months;

2. Side effects, timepoint:16 months;

3. Psychological assessment, timepoint: 16 months;

4. Quality of life, timepoint: 16 months;

5. Costs and productivity losses, timepoint: 16 months;

6. Credibility and expectancy, timepoint: 16 months.

Study description

Background summary

Epilepsy is a cost-intensive neurological disorder, characterized by recurrent unprovoked seizures. In addition to the economic burden, epilepsy imposes a substantial burden on the patients themselves and their surroundings. Patients with uncontrolled epilepsy heavily depend on informal care and health care professionals. Although, epilepsy is treatable with anti-epileptic drugs in the majority of cases, about 30% of patients suffer from drug-resistant epilepsy. The Ketogenic diet is a last resort treatment for these children. Currently, the Ketogenic diet as a treatment option for children is often overlooked and underutilized. However, the beneficial effect of Ketogenic diet has been proven in multiple observational studies, reviews, and one randomized controlled trial but there is still lack of information about the cost-effectiveness. In the current study we will evaluate the (cost-) effectiveness of the Ketogenic Diet, compared to a waiting list, in children and adolescents with refractory epilepsy between 1 and 18 years of age.

Name study: KOEK (NL:KOsten-Effectiviteit van het Ketogeen dieet).

Study objective

We hypothesize that the Ketogenic diet will be cost-effective compared to usual care.

Study design

Baseline (4 week period), visit 6 weeks and 4 months (after end baseline), 3, 6, 9, 12 months

follow-up (after end intervention period).

Intervention

Ketogenic diet:

The Ketogenic diet is calculated on an individual basis by the dietician and is introduced during a hospitalization of 1 week. The anti-epileptic drugs the children and adolescents use at the time of inclusion in the study will be continued without changes (except when medically indicated). The initial calorie prescription for the Ketogenic diet is based on an average between the pre-diet intake and the recommendations for energy requirements, taking into account current and previous weight and height, recommended calorific requirements and levels of physical activity.

Waiting list control group:

In the event of the patient being randomized into the waiting list, he or she receive their usual care, which means that they will continue to take their anti-epileptic drugs and no changes will be made to the anti-epileptic drugs treatment. Since a Ketogenic diet is a last resort treatment, the children in the control group will also receive a Ketogenic diet after a 4-month delay. The controls will be treated and monitored according to the same protocol as described in this proposal; however, this is not part of our proposed study.

Contacts

Public
Postbus 61
H.J.M. Majoie
Epilepsiecentrum Kempenhaeghe
Heeze 5590 AB
The Netherlands
+31 (0)40 2279263
Scientific
Postbus 61
H.J.M. Majoie
Epilepsiecentrum Kempenhaeghe
Heeze 5590 AB
The Netherlands
+31 (0)40 2279263

Eligibility criteria

Inclusion criteria

Children and adolescents between 1-18 years old with intractable epilepsy.

Exclusion criteria

1. Fatty acid oxidation disorders and related diseases;

2. Diabetes and hyperinsulinism;

3. Prolonged QT-time syndrome;

4. Hypercholesterolemia, hypertriglyceridemia;

5. Severe liver, kidney or pancreas diseases;

6. Renal tubular acidosis;

7. Treatment with topiramate or acetazolamide and a positive family history or other risk factors for kidney stones or acidosis;

8. Severe behavioural disorder;

9. Malnutrition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-09-2010
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	NL2391
NTR-old	NTR2498
Other	METC : 10-018/K
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A