The modified Atkins diet for epilepsy: an RCT.

No registrations found.

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

Summary

ID

NL-OMON21112

Source
NTR

Health condition

Keywords:
Refractory Epilepsy
Intellectual disability
Modified Atkins Diet

In Dutch:
Refractaire epilepsie
Verstandelijke beperking
Gemodificeerde Atkins dieet

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Source(s) of monetary or material Support: Specialistisch Behandelcentrum Zandheuvelweg
Commissie Wetenschap Tergooiziekenhuizen

Intervention

Outcome measures

Primary outcome

The main study parameter will be the number of responders 4 months after randomization, compared between the intervention and the control group. Responder is defined by >50% reduction in seizure frequency.

Secondary outcome

Retention of the diet; change in daily functioning; feasibility of the MAD in this population and setting; adverse events attributable to the MAD; predictive factors of efficacy of the diet.

Study description

Background summary

Epilepsy is one of the most common chronic neurological disorders. It affects approximately 14-44% of the people with intellectual disabilities (ID) and depending on the underlying etiology of the ID, the prevalence can be as high as 66%. Of all patients with epilepsy, approximately 30% will continue to have seizures and thus remain refractory to medical treatments. In patients with intellectual difficulties, this number is probably higher.
In children with refractory epilepsy, a beneficial effect of the ketogenic diet has been demonstrated. In adolescents and adults the ketogenic diet is less often used due to expected non- compliance to this very restricted diet. The last ten years, studies have been published evaluating the effect of the Modified Atkins diet (MAD) – a less restricted form of the ketogenic diet – on the seizure frequency in children and adults with refractory epilepsy. These studies showed a high tolerability and efficacy of the modified Atkins diet on seizure control in drug resistant epilepsy. So far, data on efficacy of the MAD in adult patients with ID and refractory epilepsy is lacking. We expect that, in this population the MAD will have a beneficial effect in reducing seizure frequency as well.

The main objective is to evaluate the effect of the modified Atkins diet on the seizure frequency of institutionalized adults with refractory epilepsy and severe intellectual disabilities.

This study will be a prospective open-label randomized controlled trial.

The study population includes adult patients (age >18 years) with severe intellectual disability and refractory epilepsy. Patients will be recruited from ‘Sherpa’ or ‘Amerpoort’, institutions for people with intellectual disabilities, in Baarn, the Netherlands.

The intervention group will be treated with the MAD for at least 4 months, with a total follow-up of at least 6 months. After the 4-month trial period, the control group can be started on the MAD as well.

To analyse the efficacy of the Modified Atkins diet (MAD), defined as 50% reduction in seizure frequency at 4 months, compared to a control group.

The secondary objectives are: to analyse retention rate of the MAD in this population, as a measure of overall effectiveness; to analyse the efficacy of the MAD, defined as improvement of daily functioning, studied with the Habilitative Improvement Scale (HIS); to assess the feasibility of the MAD in this population and this setting, with respect to logistics and adherence; to assess (serious) adverse events attributable to the MAD; to analyse which factors are associated with efficacy of the diet.

Study objective

The MAD is effective in reducing seizure frequency in patients with refractory epilepsy and severe intellectual disabilities.

Study design

Patients will visit the outpatient department after 6 weeks and 4 months

Intervention

The intervention group will be treated with the MAD for at least 4 months, with a total follow-up of at least 6 months. After the 4-month trial period, the control group can be started on the MAD as well, in which we will also evaluate efficacy, tolerability and safety.

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Eligibility criteria

Inclusion criteria

• Age > 18 years, moderate to severe ID;

• Refractory epilepsy, defined as failure of two tolerated and appropriately chosen and used AED schedules;

• More than two seizures per month, which are judged by the carers and the treating physician to impose a significant impact on the patients' QOL –-justifying treatment;

• Informed consent obtained by at least one legal representative;

Exclusion criteria

• Undergone epilepsy surgery in the last 6 months, or awaiting presurgical evaluation;

• Underwent implantation of a vagal nerve stimulation in the last 6 months;

• Previous use of the MAD or the KD for more than 7 days in the last year prior to inclusion;

• Hypercholesterolemia (total cholesterol >8), known cardiovascular disease or kidney failure, known metabolic disorders;

• Severe underweight, defined as a BMI < 16.5;

• Diabetes Mellitus.

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):	08-01-2014
Enrollment:	54
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-08-2013
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	NL3926
NTR-old	NTR4149
Other	- : -
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A