The modified Atkins diet in patients with refractory epilepsy and severe intellectual disability: a randomized controlled trial.

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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 disability.

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

Summary

ID

NL-OMON40609

Source
ToetsingOnline

Brief title
The modified Atkins diet in epilepsy: an RCT.

Condition

- Seizures (incl subtypes)

Synonym
Refractory epilepsy - Drug-resistant epilepsy

Research involving
Human

Sponsors and support

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

Zandheuvelweg;Wetenschapscommissie Tergooi;eigen bijdrage van de "Amerpoort"

Intervention

Keyword: Intellectual disability, Modified Atkins Diet, Refractory Epilepsy

Outcome measures

Primary outcome

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.

Secondary outcome

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 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 disability, 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.

Study objective

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 disability.

Study design

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

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.

Study burden and risks

The MAD is a less strict form of the ketogenic diet, a well-known and worldwide-implemented treatment for refractory epilepsy in children. Based on current findings in literature the MAD appears to be well tolerable with minimal side effects. This proposed study is therefore considered a low-risk study. The burden for the patients and caregivers will be kept to a minimum. The burden for the caregivers and legal representatives include strict keeping of a seizure dairy, not different from everyday clinical practice in the institution, monitoring side effects, weekly monitoring of ketosis and weight and filling in the HIS questionnaires after the run-in period and the 4 month trial period.
The burden for patients includes adherence to the diet regime and laboratory investigations, which will be kept to a minimum. Patients will be monitored carefully for any possible side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 pre-surgical 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), cardiovascular disease or kidney failure, metabolic disorders known to deteriorate after fasting;
• 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2014
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-03-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-12-2014

Application type:	Amendment
Review commission:	METC NedMec

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	NL44058.041.13

Study results

Date completed:	22-03-2017
Actual enrolment:	29