Effectiveness of ketogenic diet on excessive daytime sleepiness in adults with narcolepsy type 1: a proof of concept study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON51890

Source
ToetsingOnline

Brief title
Effectiveness of ketogenic diet in narcolepsy type 1

Condition

- Sleep disturbances (incl subtypes)

Synonym
low-carbohydrate high-fat

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland

Source(s) of monetary or material Support: Stichting Wakker Worden Wakker Worden

Intervention

Keyword: diet, ketogenic, narcolepsy, sleepiness

Outcome measures

Primary outcome

Primary endpoint of the study is sleep latency on the Maintenance of

Wakefulness Test (MWT).

Secondary outcome

Secondary parameters are sustained attention using the Sustained Attention to

Response Task (SART), the self-reported EDS. mental wellbeing, sleep quality,

ADHD symptoms, cataplexy, and feasibility of the ketogenic diet.

Study description

Background summary

Narcolepsy type 1 (NT1) is a rare neurologic sleep-wake disorder, caused by hypocretin insufficiency. It is characterized by various invalidating symptoms, such as an inability to stay awake during the day, an inability to stay asleep at night, excessive daytime sleepiness (EDS), difficulty with alertness, vigilance, attention, concentration, and they often experience sudden loss of muscle tonus after a strong emotion (cataplexy), hypnagogic hallucinations, and sleep paralysis. Moreover, patients with NT1 complain about memory difficulties, automatic behavior, tiredness, mood and depressive symptoms, anxiety, and they often become overweight or obese in the first stage of developing NT1. Currently, the most effective treatment for the symptoms of NT1 is medication and lifestyle advice, such as taking regular naps during the day. Our clinical experience indicates that minimizing carbohydrate intake may reduce EDS, and also helps them stay alert or to have a better focus for longer periods of time during the day. Previous research showed that a ketogenic diet (KD) (a low/non-carbohydrate diet) had a positive effect on self-reported EDS in a group of patients with NT1.

Study objective

This study comprises a first proof of concept. The primary aim is to investigate the effect of a ketogenic diet on EDS and sustained attention in adult NT1 patients. Secondary aims are to investigate if a ketogenic diet improves weight reduction, any improvements in sleep during the night and adherence to a ketogenic diet in narcolepsy type 1 patients.

Study design

Proof-of-concept (pilot) intervention study.

Intervention

All participants follow a ketogenic diet as instructed and monitored by a certified dietician for 12 weeks. Then participants are asked to continue the diet without guidance by a dietician. Outcomes are measured at baseline (week 1), at the end of the guided diet (week 13), and at study end (week 25). Prior to each measurement participants will wear actigraphy, measuring sleep and wake periodes by movement and light. ketones in blood and/or urine samples are monitored during the study in order to evaluate if the diet intervention has succeeded.

Study burden and risks

Participants are asked to visit the study site (SEIN, Heemstede) five times; twice at baseline, twice at week 13 and once at week 25. The fist visits in weeks 1 and 13 will take 45-60 minutes, and involves the attachment of the electrodes and sensors to the head, face, and on the body of the participant. On full study days in weeks 1, 13, and 25, various tests will be done (MWT, SART), blood is drawn (fingertip blood sample), questionnaires are filled out, physical measurements (weight, fat%) are done. Participants will also have an interview with the dietician. Between baseline and week 13, participants regularly have contact with the dietician by telephone or e-mail. Throughout the study participants will verify if they are in a state of ketosis via urinary strips measuring ketones.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of narcolepsy type 1 as classified by the International Classification of Sleep Disorders-3 (ICSD-3)
18 years or older
Motivated to commit to the diet

Exclusion criteria

Underweight (BMI < 18.5)
Diabetes Mellitus
Thyroid disfunction
mental / psychiatric difficulties
use of y-hydroxybutyrate
pregnant or lactating women or women trying to conceive
excessive drug or alcohol use

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2022
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	28-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76672.058.21