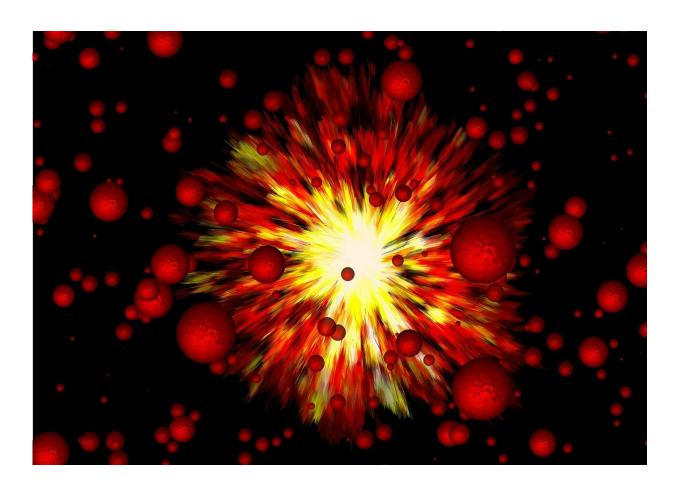


New dietary treatment for epilepsy well tolerated and reduced seizures

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The first clinical trial of a new dietary treatment for children and adults with severe forms of epilepsy, co-developed by UCL researchers and



based on the ketogenic diet, has been successfully completed.

For the study, published in *Brain Communications*, clinicians evaluated the use of K.Vita, (also known as Betashot), an oral liquid dietary supplement developed by UCL in collaboration with Royal Holloway, University of London, and Vitaflo International Ltd.

The <u>ketogenic diet</u> (KD) consists of high-fat, low-carbohydrate and adequate protein consumption and mimics the fasting state, altering the metabolism to use <u>body fat</u> as the primary fuel source. This switch from carbohydrates to fat for body fuel is known as ketosis.

It is widely used to treat drug resistant epilepsies. However, the highly restrictive <u>diet</u>, which can cause constipation, low blood sugar, and stomach problems, can have poor compliance and is not suitable for everyone. Some KD supplements are also known to be unappetising.

K.Vita is based on novel findings by UCL researchers, who discovered a different underlying mechanism to explain why the KD is effective against epilepsy; in developing a new treatment, researchers also sought to reduce the adverse side effects caused by KD.

Corresponding author Professor Matthew Walker (UCL Queen Square Institute of Neurology) said: "The ketogenic diet has been used for 100 years to treat epilepsy, helping reduce seizures in both children and adults.

"It has long been thought the diet was effective due to its production of ketones, however we now believe the increase in levels of the fatty acid, decanoic acid, also produced by the diet, may provide the powerful antiseizure effects.

"In this study we evaluated a newly developed medium chain triglyceride



(type of dietary fat) supplement, designed to increase levels of decanoic acid, while also reducing the <u>adverse side effects</u>, and to be more palatable."

For the feasibility trial, researchers wanted to establish participants' tolerance (side effects such as bloating or cramps) to the treatment, acceptability (flavour, texture, taste) and compliance (how easy it is to use K.Vita at the advised quantity, as part of their daily diet).

As secondary outcomes, they also monitored the frequency of epileptic seizures or paroxysmal events (fits, attacks, convulsions) and whether ketone production was decreased.

In total, 35 children (aged 3 to 18) with genetically caused epilepsy and known to be unresponsive to drugs, and 26 adults with drug-resistant epilepsy (DRE), were given K.Vita liquid supplements (a drink), to be taken with meals. They were also asked to limit high-refined sugary food and beverages from their diets.

The trial lasted 12 weeks with K.Vita treatments increasing incrementally over time, taking into account individuals' tolerance to the treatment.

In total, 23/35 (66%) children and 18/26 (69%) adults completed the trial i.e they were continuing to take K.Vita at 12 weeks. Gastrointestinal disturbances were the primary reason for discontinuation, and their incidence decreased over time

Over three-quarters of participants/caregivers reported favourably on sensory attributes, such as taste, texture and appearance, and ease of use.

In regards to the secondary outcomes, there was a mean 50% reduction in seizures or paroxysmal events, and fewer than 10% of people on the



diet produced significant ketones.

Commenting on the findings, Professor Walker, who is also a consultant neurologist at the National Hospital for Neurology and Neurosurgery, said: "Our study provides early evidence of the tolerability and effectiveness of a new <u>dietary supplement</u> in severe drug-resistant epilepsies in adults and children and provides a further treatment option in these devastating conditions.

"It also offers an alternative, more liberal, diet for those who cannot tolerate or do not have access to ketogenic diets."

He added: "While this study was not designed to include enough patients to fully assess the supplement's effects on seizures, it is exciting to report that there was a statistically significant reduction in the number of seizures in the group overall after three months of treatment.

"Furthermore, high ketone levels were not observed in over 90% of the participants. This indicates that the effect of the diet was independent from ketosis; this is important because high ketone levels in the ketogenic diets contribute to both short- and longer-term side effects."

First author, Dr. Natasha Schoeler, Research Dietitian at UCL Great Ormond Street Institute of Child Health, commented: "This novel dietary approach for epilepsy management involves following the principles of a healthy balanced diet alongside use of K.Vita, allowing greater dietary freedom compared to ketogenic diets. Our approach also requires much less input from a specialist dietician than is required by traditional ketogenic diets, and so may allow more widespread access to people with drug-resistant epilepsy."

Researchers say larger, controlled studies of K.Vita are now needed to determine the precise epilepsies and conditions in which the supplement



is most effective.

More information: K.Vita®: a feasibility study of a blend of medium chain triglycerides to manage drug-resistant epilepsy, Brain Communications (2021). DOI: 10.1093/brain/fcab160

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