



Clinical Trial Summary

K·Vita: a feasibility study of a blend of medium chain triglycerides (MCT) to manage drug-resistant epilepsy (DRE)

ClinicalTrials.gov Identifier: NCT02825745



What is K·Vita?

K·Vita is a ready-to-use, palatable, thickened flavoured liquid containing 80:20 C10:C8 triglyceride, in 120ml packs.

Study Sites:

Great Ormond Street Hospital for Children, London, UK,
The National Hospital for Neurology and Neurosurgery, London, UK
and The Chalfont Centre for Epilepsy, Chalfont-St-Peter, UK.

Study Period:

July 2016 to March 2018.



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Study Objectives

A 12 week, prospective feasibility study of the use of K·Vita, an MCT food for special medical purposes (FSMP) for the dietary management of children and adults with DRE.

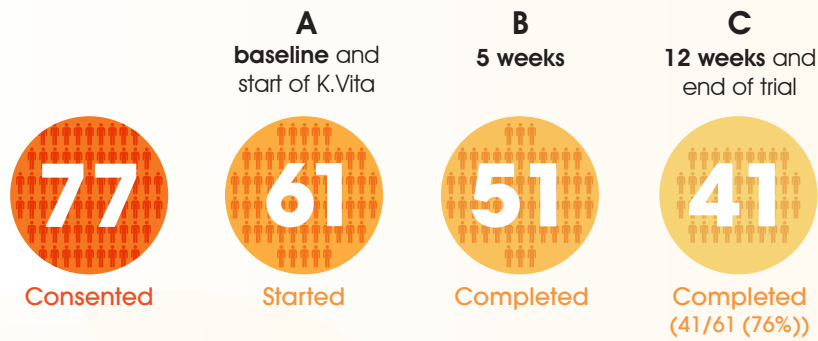
Primary objectives were to evaluate K·Vita for:

- Tolerability**
- Acceptability**
- Compliance**

Secondary objective:

- Seizure Monitoring**

The study consisted of three visits:

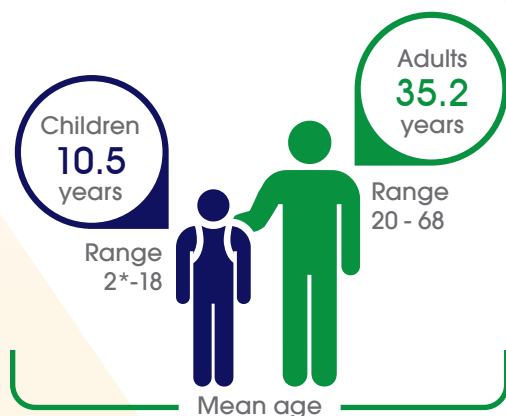
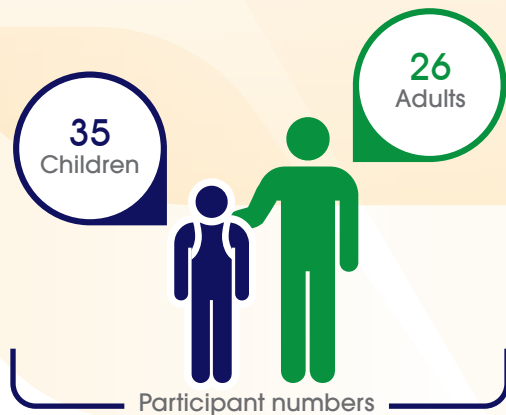


K·Vita was taken as part of the participant's usual diet, whilst avoiding foods and beverages high in sugar to optimise nutritional intakes.

Demographics

Participants were aged from 3* years with epileptic seizures, or associated paroxysmal non-epileptic events (for individuals with glucose transporter type 1 deficiency syndrome [GLUT1-DS] or Alternating Hemiplegia of Childhood [AHC]), despite adequate levels of antiseizure drugs (ASDs).

* prescribed for one patient under the age of 3 years at investigators discretion.



Participants completing the study had **previously tried a median of:**
children: 3 ASDs
adults: 10 ASDs



(52/61) of participants had previously tried, failed, had no access to or were unable to start the ketogenic diet (KD).

Results

66% children and **69% adults** completed the trial.

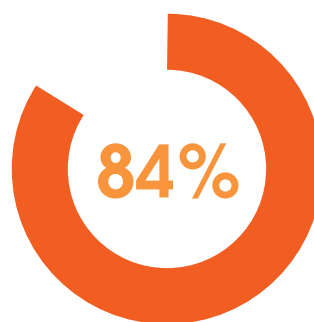
Primary outcomes:

Tolerability

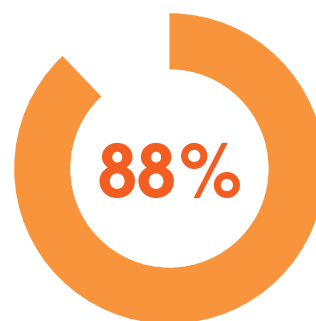
Overall, **K-Vita** was well-tolerated, with initial GI symptoms resolving with a flexible and gradual approach to its introduction.

Acceptability

Of 15 caregivers and 19 adults (total 34) who returned an acceptability questionnaire at Visit C:



Agreed or strongly agreed **K-Vita** had a good flavour & taste.



Agreed or strongly agreed **K-Vita** was easy to use.

Compliance

For child and adult participants for whom data are available*

74%

28/38* participants were taking **100%** of their prescribed amount of **K-Vita** at their Visit C review

*14/21 children & 14/17 adults

Secondary Outcome: Seizures and paroxysmal events

Statistical modelling shows an estimated $\geq 50\%$ reduction of seizures or paroxysmal events.

 **38%** (6/16)
Children

 **50%** (8/16)
Adults

Reduction in seizures or paroxysmal events correlated significantly with blood concentrations of C8 and C10, but not beta hydroxybutyrate.

Conclusion

- Consumption of K-Vita, alongside dietary advice, was generally **well accepted, tolerated and complied with**
- Of those completing the study, the **majority (>75%) continued to take K.Vita**
- Despite not being a primary outcome of the study, a **significant reduction in frequency of seizures, or paroxysmal events was observed** for some participants

K-Vita can provide an effective, simpler, less restrictive and more accessible approach to the dietary management of DRE in children and adults who are unable to manage or access the support to implement a KD.

To review the paper in Brain Communications please visit www.k-vita.co.uk

Schoeler, N.E., et al. K. Vita: a feasibility study of a blend of medium chain triglycerides to manage drug-resistant epilepsy. Brain communications, 3(4), p.fcab160.

K-Vita is a Food for special medical purposes, for use under medical supervision.

This is intended for healthcare professionals.

Positive change through the power of nutrition



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