A 4:1 ketogenic diet to acute stroke patients is safe and feasible
- a randomized controlled trial

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Abstract

Background and Purpose -- Ketone bodies can meet more than 60% of the brain’s energy needs. Controlled studies consistently show neuroprotective effects in ketotic rodents with induced ischemia. We studied the safety and feasibility of a ketogenic diet to acute stroke patients and investigated potential neuroprotective effects.

Methods -- Patients were randomized to a ketogenic diet or a standard hospital diet for one week within 72 hours of symptom onset at three neighboring hospitals in Copenhagen. The ketogenic diet consisted of 4:1 ketogenic dishes and Ketocal® (Nutricia). Primary endpoints were function (NIHSS, Barthel 100, MRS), fasting b-glucose and p-C-peptide. Secondary endpoints included nutritional intake, gastrointestinal complications, lipids and blood markers for safety and ketosis.

Results -- 17 patients were randomized to intervention (n=6) and control (n=11). Differences were found for b-β-hydroxybutyrate (p=0.001), p-INR (0.05) and p-phosphate (0.009) (baseline to 7 days) and p-alkaline phosphatase (p=0.05) (baseline to 30 days). Three of six patients developed ketosis (>1.5mmol/l) at a median time of 2.5 days. Patients on the ketogenic diet had a higher
energy intake (p=0.005), representing a median of 86% of estimated requirements compared to 52% in the control group (p=0.018).

**Conclusions** -- A 4:1 ketogenic diet is safe and well tolerated by patients with acute stroke. The diet increased energy intake, but the degree of ketosis was insufficient for potential neuroprotective effects. New methods for inducing acute ketosis are necessary, if potential clinically relevant effects are to be revealed.

**Clinical Trial Registration Information** -- URL: [http://www.clinicaltrials.gov](http://www.clinicaltrials.gov). Unique identifier: NCT01997749.