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## The ERGO trial: A pilot study of a ketogenic diet in patients with recurrent glioblastoma.

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### Abstract

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**Background:** Increased reliance on aerobic glycolysis and suppressed mitochondrial respiration are hallmarks of cancer (Warburg Effect). Because normal tissues can satisfy energy demands largely through ketone bodies, glucose- antagonistic therapies have potential as cancer-selective interventions. Ketogenic diets, apart from their anticonvulsive activity, may reduce blood glucose levels, and case studies suggested clinical activity in glioma patients. To assess feasibility and safety of a ketogenic diet in patients with glioblastoma, we conducted a prospective trial (NCT00575146).

**Methods:** 19 patients with glioblastoma recurrent after radiotherapy were put on a ketogenic diet restricting carbohydrate intake and containing lactate drinks and oils. Metabolic markers, ketones in the urine and body weight were monitored. MRI was performed every 6 weeks. Quality of life was regularly assessed.

**Results:** 18 patients were evaluable. No diet-related serious adverse events occurred. Adherence to the diet was good. Two patients discontinued the diet in the absence of tumor progression. Ketosis was achieved in 85% of the evaluable patients. Three patients had stable disease after 6 weeks. One patient achieved a minor response. Median PFS was 5 weeks (range 3-13 weeks). At first progression on the diet, the protocol allowed addition of a salvage therapy which consisted of bevacizumab in 7 patients. In these, objective response rate was 86%, median PFS from start of cotreatment was 19.7 weeks (range 12-55+ weeks), PFS 6 was 43%.

**Conclusions:** This ketogenic diet is feasible and safe and has antitumor activity in glioma patients. The combination of the diet with antiangiogenic agents appears promising according to theoretical considerations and our preliminary data. Randomized trials evaluating the therapeutic potential of ketogenic diets in tumor patients are warranted.

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