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A phase IIa clinical biomarker trial of aspirin and dietary arginine restriction in colorectal cancer patients.

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Abstract

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Background: Colorectal cancer (CRC) patients are at high risk for recurrence and for secondary CRC development. Our preliminary findings provide a rationale for reducing tissue polyamines as tertiary chemoprevention in local and locally-advanced CRC patients. We will attempt to demonstrate rectal tissue putrescine reduction in stage I-III, optimally-treated CRC patients after treatment with dietary arginine restriction + daily oral aspirin in a phase IIa clinical biomarker trial. **Methods:** 24 participants will be treated with aspirin and an individualized dietary regimen to reduce arginine intake by >30% during the 12-week intervention. Sample size calculations were based on the Binomial test for a single proportion, to yield 80% Power. Six patients will receive psychosocial telephone counseling (PTC). Endoscopy with serial biopsies, phlebotomy, and urine collection will be performed pre- and post-intervention to assess potential biomarkers. The primary endpoint is a > 50% decrease in rectal tissue putrescine levels from baseline, as a measure of polyamine reduction in the target tissue of CRC patients. Secondary aims include: to demonstrate significant alterations in secondary endpoint biomarkers relevant to polyamine metabolism in CRC patients, including rectal mucosa *Odc1 and Ssat* expression and urinary polyamine metabolites; to determine this intervention's side-effect profile in a population of optimally-treated CRC patients; to determine the efficacy of accrual to this novel type of clinical trial involving dietary intervention and oral aspirin therapy among a group of potentially cured cancer patients for whom there is currently no recommended further therapy; to assess feasibility of PTC and collect pilot data regarding the influence of PTC on compliance with the dietary prescription and compliance with aspirin, and if PTC further influences healthy exercise, reduced fatigue and improved quality of life when compared to the non-counseled cohort. Hypothesis: Among optimally-treated stage I-III CRC patients, a 12-week intervention of daily aspirin and a low-meat, arginine-restricted diet will favorably alter polyamine-related tissue, serum, and urinary biomarker levels.