

## General Evidence

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
<p>Hamaguchi, R., Tsuchiya, T., Miyata, G., Sato, T., Takahashi, K., Miura, K., Oshio, H., . . . Iwase, S. (2020). Efficacy of oral administration of cystine and theanine in colorectal cancer patients undergoing capecitabine-based adjuvant chemotherapy after surgery: A multi-institutional, randomized, double-blinded, placebo-controlled, phase II trial (JORTC-CAM03). <i>Supportive Care in Cancer</i>, 28(8), 3649–3657. <a href="https://doi.org/10.1007/s00520-019-05205-1">https://doi.org/10.1007/s00520-019-05205-1</a></p>	<p><b>Design:</b> Randomized double-blinded, placebo-controlled phase 2 trial</p> <p><b>Methods:</b> Patients either received cystine and theanine in the form of L-cystine 700 mg and L-theanine 280 mg or a placebo in 1 dose every morning from the start of capecitabine therapy through cycle 4. Supportive care for hand-foot syndrome (HFS) was permitted.</p> <p><b>Sample:</b> 100 patients with colorectal cancer (CRC) (52 in intervention group, 48 in placebo control group), 60% male, 40% female, median age 63.5 years in intervention group and 65.5 years in control group</p> <p><b>Setting:</b> Multicenter (7) ambulatory care throughout Japan</p>	<p><b>Independent Variable:</b> L-cystine 700 mg and L-theanine 280 mg</p> <p><b>Dependent Variable:</b> Primary endpoint: Incidence rate of diarrhea grade 1 or higher</p> <p>Secondary endpoints: HFS of grade 1 or higher, diarrhea of grade 2 or higher, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30 (EORTC QLQ-C30) and EORTC QLQ–Colorectal Cancer Module (CR29) scores, protocol adherence, completion rate of 4 cycles, proportion of completion without delay or dose reduction, time to completion of 4 cycles, and total dose of capecitabine.</p>	<p>Incidence/severity of diarrhea</p> <p>HFS incidence and severity as determined by the Common Terminology Criteria for Adverse Events (CTCAE), version 4.0</p> <p>Completion and dose delay in capecitabine therapy</p> <p>EORTC QLQ-C30 and EORTC QLQ-CR29</p>	<p>Incidence rate of grade 1 or higher diarrhea tended to be lower in the cystine and theanine group than in the placebo group (18.4% versus 28.9%, <math>p = 0.169</math>)</p> <p>Incidence rate using CTCAE version 4.0, Japanese Clinical Oncology Group version, for HFS of grade 1 or higher was lower in the cystine and theanine group than the placebo group, although this was not statistically significant (67.4% versus 77.8%, <math>p = 0.185</math>, and 67.3% versus 80%, <math>p = 0.124</math>).</p> <p>EORTC QLQ-C30 and EORTC QLQ-CR29 scores revealed that the cystine and theanine group had fewer constipation symptoms and better cognitive function than the placebo group; however, differences were not significant.</p> <p>The completion rate of 4 courses of capecitabine treatment without delay or dose reduction, time to completion of 4 courses, and total dose of capecitabine were investigated; there were no significant differences between the 2 groups.</p> <p>No significant increases of incidence of grade 2 or higher adverse events were associated with the intervention group.</p>	<p>Findings were not easily generalizable.</p> <p>Use of supportive measures for HFS may have influenced results.</p> <p>Small sample size</p>	<p>The findings are valid and reliable.</p> <p>Findings are not generalizable beyond patients receiving capecitabine for CRC.</p> <p>This is a complementary therapy that could potentially provide some measure of assistance in decreasing the incidence or severity of common adverse events with capecitabine therapy, including a 10% reduction in diarrhea.</p> <p>The best nursing intervention is education about supportive measures for HFS and diarrhea.</p> <p>Knowing these results and those of other potential complementary therapies can assist in educating patients about their efficacy or lack of efficacy.</p> <p>Educate patients about starting supportive measures, including moisturizers, avoidance of pressure, prevention of injury, and elevation or cooling of the hands and feet for HFS, as well as education about probiotics or loperamide as symptomatic treatments for diarrhea.</p>