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Phase III trial finds high-dose vitamin D does not improve colorectal cancer outcomes

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The SOLARIS trial found no significant improvement in progression-free survival, response rates or overall survival when high-dose vitamin D3 was added to standard treatment.



A Phase III clinical trial has found that adding high-dose vitamin D3 to chemotherapy and bevacizumab does not improve progression-free survival among patients with previously untreated metastatic colorectal cancer.

The multicentre, double-blind SOLARIS trial enrolled 455 patients through the US National Clinical Trials Network between October 2019 and December 2022.

Participants received either modified FOLFOX6 or FOLFIRI chemotherapy with bevacizumab every two weeks.

They were randomly assigned to receive either high-dose or standard-dose vitamin D3 alongside treatment.

Patients in the high-dose group received 8,000 international units of vitamin D3 daily for 14 days, followed by 4,000 international units per day. Patients in the control group received 400 international units daily.

Median progression-free survival was 11.8 months among patients receiving high-dose vitamin D3 and 10.3 months among those receiving the standard dose.

The difference was not statistically significant.

The objective response rate was 51% in the high-dose group and 44% in the standard-dose group. This difference also did not reach statistical significance.

Median overall survival was 25.6 months among patients receiving high-dose vitamin D3 and 27 months among those receiving the standard dose.

Researchers found no clinically meaningful differences in the most common grade 3 or higher adverse events.

Neutropenia occurred in 32% of patients in the high-dose group and 30% of those in the standard-dose group.

Grade 3 or higher hypertension was reported in 20% and 23% of patients, respectively. The incidence of adverse effects associated with vitamin D was also similar between the two groups.

The trial was conducted following earlier Phase II findings suggesting that high-dose vitamin D3 could improve progression-free survival when added to standard treatment.

The Phase III results showed that high-dose vitamin D3 did not improve progression-free survival, objective response or overall survival when added to chemotherapy and bevacizumab for previously untreated metastatic colorectal cancer.