

## GM1 for taxane-induced neuropathy in breast cancer

In patients with breast cancer receiving taxane-based chemotherapy, treatment with ganglioside-monosialic acid (GM1)—a monosialo-glycosphingolipid with neuroprotective functions—could decrease the incidence and severity of taxane-induced peripheral neuropathy, according to a recent study.

Yanhong Su (Sun Yat-Sen University Cancer Center, Guangzhou, China) and colleagues did a double-blind, randomised, placebo-controlled, phase 3 trial in China, between May, 2015, and November, 2016, in patients with early-stage breast cancer receiving taxane-based adjuvant chemotherapy. Patients were randomly assigned (1:1) to receive GM1 (n=103; 80 mg once per day on days -1, 1, and 2) or placebo (n=103). Functional Assessment of Cancer Treatment Neurotoxicity (FACT-Ntx) subscale scores at 2 weeks (after four chemotherapy cycles) was the

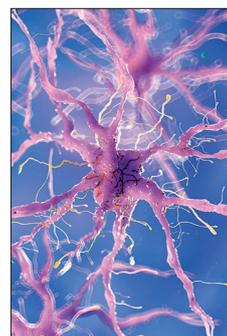
primary endpoint. Secondary endpoints included neurotoxicity assessed by Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 scale and Eastern Cooperative Oncology Group neuropathy scale (ENS).

In 183 assessable patients, the mean FACT-Ntx subscale score was 43.27 (95% CI 43.05–43.49) in the GM1 group versus 34.34 (33.78–34.89) in the placebo group (mean difference 8.96, 95% CI 8.38–9.54,  $p<0.001$ ). Fewer patients in the GM1 group had grade 1 or worse peripheral neurotoxicity (as measured with CTCAE 4.0) than in the placebo group (13 [14%] vs 92 [100%],  $p<0.001$ ). Fewer patients in the GM1 group had grade 1 or worse neurotoxicity (as measured by ENS) than in the placebo group (24 [26%] vs 90 [98%],  $p<0.001$ ). The incidence of grade 3 or worse adverse events was not significantly different between groups (2% with GM1

vs 8% with placebo,  $p=0.06$ ); no grade 4 adverse events were reported.

Co-author Joseph Unger (Fred Hutchinson Cancer Research Center, Seattle, WA, USA) said, "Many strategies to prevent chemotherapy-induced neuropathy have been unsuccessful in trials. This finding is the first strong evidence of an effective intervention to protect against the development of this painful condition." "The long-term effects of GM1 on taxane-induced peripheral neuropathy as well as the possible different efficacies in various populations remain to be further studied," added Su. Mark Robson (Memorial Sloan Kettering Cancer Center, NY, USA) commented, "This treatment could be a significant advance provided that it does not influence the efficacy of taxane treatment."

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Published Online  
May 23, 2019

[http://dx.doi.org/10.1016/S1470-2045\(19\)30373-0](http://dx.doi.org/10.1016/S1470-2045(19)30373-0)

For the study by Su and colleagues see *J Natl Cancer Inst* 2019; published online May 15.  
DOI:10.1093/jnci/djz086