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OXTOX Lay Summary

OXTOX: Can Oxaliplatin dose reduction and neurotoxicity be reduced with ibudilast in people with metastatic colorectal cancer? A phase II randomised study

Oxaliplatin chemotherapy improves survival but causes acute neuropathy (discomfort on touching or swallowing cold objects or fluids) and chronic chemotherapy-induced peripheral neuropathy (CIPN) (pins and needles) in most people receiving the drug. This causes numbness, discomfort, and pain especially in the hands and feet, which can last for months to years after stopping treatment. It has a major impact on quality of life, functional status and return to daily life, and there is no effective prevention or treatment. CIPN is the most common cause of people needing a reduction in their dose of oxaliplatin or having to stop the treatment early. Acute neurotoxicity is associated with CIPN.

Studies done using animal models suggest ibudilast, a tablet, when given with oxaliplatin can prevent and treat neurotoxicity. This may mean more oxaliplatin can be delivered, thus improving survival in people with colorectal cancers.

In this study we will randomise (1:1) 100 people to receive either ibudilast or placebo with their chemotherapy to see whether ibudilast decreases the severity of acute neuropathy and enables people with metastatic colorectal cancer to get more oxaliplatin before needing dose modifications for CIPN. Acute neurotoxicity is measured at day 1 and 3 of each cycle and all other measures at day 1 of each cycle and then 1, 3, 6, 9 and 12 months after chemotherapy. Assessments include CIPN, functional status, quality of life, toxicity, oxaliplatin dose and modifications, and progression-free survival.