Study of intravenous mistletoe extract to treat advanced cancer

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In Texas, the type of mistletoe you'll find on trees typically has white berries in clusters. Credit: Pixabay/CC0 Public Domain

Mistletoe extract has been widely used to support cancer therapy and improve quality of life, but there has been a lack of clinical trials and data to support its use. Researchers at the Johns Hopkins Kimmel Cancer Center completed what is believed to be the first phase I trial of intravenous Helixor M in the U.S. aimed at determining dosing for subsequent clinical trials and to evaluate safety.

The findings from the small study were reported in *Cancer Research Communications*.

The trial's purpose was to evaluate the drug's safety, but the researchers, led by Channing Paller, M.D., associate professor of oncology, also documented improved quality of life and some disease control.

Mistletoe extract (ME), known as Helixor M, was studied in 21 patients with advanced and treatment-resistant cancers of various types. The phase I trial used dose escalation to determine the maximum dose that could be safely tolerated by patients. ME was delivered intravenously three times per week until disease progression or until toxicity. The study concluded that dose to be 600 milligrams of ME.

The median follow-up duration on mistletoe was 15.3 weeks. Stable disease was observed in five patients and lasted, on average, for 15 weeks. Tumors in three participants decreased in size, and remained stable for two to five months, however, this did not meet official criteria for partial response. Patients also reported overall improved quality of life via a questionnaire. The most common side effects reported were fatigue, nausea, and chills and they were noted as manageable.

"Intravenous mistletoe demonstrated manageable toxicities with disease control and improved quality of life in this group of patients, who had already received multiple cancer therapies," says Paller, adding that additional phase II studies in combination with chemotherapy are the

next step, pending additional funding.

In addition, Paller says, laboratory research to better decipher ME's mechanisms are needed, as the cytokines (cell-signaling proteins) measured in this study are preliminary and hypothesis generating.

Mistletoe extract is a semi-parasitic plant with several active ingredients that, in preclinical studies, appear to directly cause the death of tumor cells and stimulate an immune response. It has been used in Europe for several decades as a complementary medicine approach to cancer treatment alone or in combination with chemotherapy and radiation therapy, but it has not been evaluated in clinical trials.

ME is not currently FDA approved for cancer treatment in the U.S. but is listed in the Homeopathic Pharmacopoeia and is offered in integrative care clinics.

More information: Channing J. Paller et al, Phase I Trial of Intravenous Mistletoe Extract in Advanced Cancer, *Cancer Research Communications* (2023). DOI: 10.1158/2767-9764.CRC-23-0002

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