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Abstract**Full text links**Cancer. 1976 Jul;38(1):119-30.**Observations following Corynebacterium parvum administration to patients with advanced malignancy. a phase I study.**Fisher B, Rubin H, Sartiano G, Ennis L, Wolmark N.**Abstract**

There has been increasing interest regarding the use of Corynebacterium parvum (CP) with other modalities in the management of primary cancer. Due to the paucity of specific information available relative to CP toxicity, a Phase I study was carried out in patients with advanced disease. The purpose of the investigation was not to evaluate the effect of CP on tumor growth. From 273 injections of CP in 40 patients it was observed that following intravenous (i.v.) infusion of CP: a) a febrile response and chills of considerable severity occurred in almost all patients and did not appreciably diminish in intensity following repetitive administrations; b) nausea, vomiting, headache, and confusion were not infrequent; c) a "flu-like" syndrome lasting 24 to 48 hours occurred following almost all courses of CP; d) blood pressure elevations occurred on occasion and were related to the severity of other side-effects; hyper- or hypo- tension was not a problem; e) there were no anaphalactic reactions. Pretreatment with a single administration of 100 mg of hydrocortisone prior to CP infusion markedly and in some instances dramatically diminished the toxicity and made acceptable the use of i.v. CP on an outpatient basis. The use of i.v. CP in patients with cerebral metastases may be hazardous. Subcutaneously administered CP resulted in a significant number of undesirable local reactions. Evaluation of delayed cutaneous hypersensitivity response, immunoglobulins, complement, and E- and EAC-rosette-forming cells during CP administration failed to demonstrate significant change from injection values. Results were similar whether hydrocortisone pretreatment was or was not employed. From the standpoint of toxicity it now seems appropriate to use i.v. CP, particularly following pretreatment with hydrocortisone, in a controlled clinical trial to evaluate its therapeutic effectiveness in the management of primary cancer.

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