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## Phase II study of viscum fraxini-2 in patients with advanced hepatocellular carcinoma.

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Hepatocellular carcinoma (HCC) is one of the most common cancers worldwide. Although a wide range of therapeutic options is available, the efficacy of these methods and the prognosis of patients with HCC remain very poor. This study was conducted to evaluate the efficacy and safety of viscum fraxini-2 in patients with chemotherapy-naive, advanced hepatocellular carcinoma. 23 patients with unresectable HCC who had received no prior systemic chemotherapy with objectively measurable tumors were enrolled on this study. The mistletoe preparation for the study is an aqueous injectable solution. It contains one milliliter of viscum fraxini in dilution stage-2 (15 mg extract of 20 mg mistletoe herb from ash tree, diluted in di-sodium-mono-hydrogen phosphate, ascorbic acid and water) which is equivalent to 10 000 ng/ml injection ampoules. 2 ampoules of viscum fraxini-2 were administered subcutaneously once weekly. As assessed by conventional imaging criteria, 3 (13.1%) patients have achieved complete response, 2 (8.1%) patients have achieved a partial response. 9 (39.1%) had progressive disease while 9 (39.1%) patients didn't have evaluation of response due to early death. The median overall survival time for all patients was 5 months (range 2-38 months), for those who achieved a CR was 29 months (range 12-38 months) and, for those who achieved a PR was 6.5 months (range 6-7 months). The median progression free survival for all patients was 2 months (range 1-38 months), for those who achieved a CR, it was 29 months (range 8-38 months) and for those who achieved a partial response, it was 5 months (range 4-6 months). No hematologic toxicity has been encountered. The spectrum of non-hematologic toxicity was mild. The WHO toxicity criteria grade 3-4 were 34.8% drug related fever, 13.1% erythema at injection site and 17.4% pain at the site of injection. No drug related discontinuation or toxic deaths have occurred. Viscum fraxini-2 seems to be particularly promising in patients with advanced HCC, it shows antitumor activity and low toxicity profile. Further studies in combination with other active agents are clearly warranted.

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