メラノーマの生存率改善（Abstract #: 20027）

Phase IIスタディの結果、sargramostimによるアジュバント療法を受けたハイリスクメラノーマ患者のほとんどが無増悪生存期間または全生存期間の改善を認めた

Phase II study suggests that most high-risk patients with melanoma who receive adjuvant treatment with sargramostim achieve disease-free or overall survival

Sargramostimおよびインターロイキン2同時投与によるアジュバント療法を受けたハイリスクメラノーマ患者のほとんどが、無増悪生存期間または全生存期間の改善を認めたとのphase IIスタディの結果がAmerican Society of Clinical Oncology学会で発表された。治癒を目的とした手術を施行された患者計45人がsargramostimおよびインターロイキン2による治療を1年間とその後sargramostimでの治療を1年間受けた。経過観察期間は1～50ヵ月であった（中央値15.9ヵ月）。トライアル終了時に45人中32人が生存していた（stage IV 13人中9人、stage III 25人中16人、stage II（3B/4C）7人中7人）。研究者らは、21ヵ月後に60%の患者が無増悪生存を、64%が生存を達成したと報告した。Sargramostimは免疫細胞機能を増強する増殖因子製剤である。筆者らはさらに大規模なphase IIIトライアルの施行を提案している。

Full Text

The majority of high-risk patients with melanoma who receive adjuvant treatment with sargramostim and the synergistic cytokine Interleukin-2 (IL-2) achieve disease-free or overall survival, according to results of a phase II trial presented at the annual meeting of the American Society of Clinical Oncology.

"Previous findings suggest that sargramostim may be a potential adjuvant therapy for high-risk melanoma patients," said E. George Elias MD, PhD, Director of Maryland Melanoma Center.

"The percentage of patients who achieved disease-free and overall survival in this trial provides further evidence that sargramostim may prove to be a viable treatment option for this patient population and that further study in Phase III trials is needed."

The study was a single-arm, open-label design in which safety, tolerability, and efficacy were tested for the combination of sargramostim and IL-2 for one year, followed by sargramostim alone for a second year.

In the first year, sargramostim was administered subcutaneously at 125mcg/m^2/day for 14 consecutive days, followed by IL-2 subcutaneously at nine million IU/m^2/day for four days. Patients then received no treatment for 10 days. Patients with resected large metastases that yielded approximately 100 x 106 tumor cells also received autologous whole cell vaccine starting at the second cycle.

During the second year, each patient received sargramostim alone two times per week. In patients who experienced resected recurrence, the same adjuvant therapy was re-administered.

Adjuvant therapy with sargramostim and IL-2 was generally well-tolerated in the 45 patients, all of whom started therapy following potentially curative surgery. Toxicities were mild to moderate and no hospitalizations were required.

Researchers reported that 60 percent of the patients experienced disease-free survival and 64 percent of patients achieved overall survival at 21 months.

Follow-up ranged from 1 to 50 months (median, 15.9 months). At the end of the trial, 32 of the original 45 patients were alive [9/13 stage IV, 16/25 stage III, and 7/7 stage II (3B/4C)].

Survival data were expressed by the Kaplan- Meier method, and showed disease-free survival of 0.60 and overall survival of 0.64 at 21 months. There was no statistical difference in survival by Log Rank testing between those who received only sargramostim versus those treated by sargramostim and IL-2, and there was no increase in the number of dendritic cells during or after sargramostim administration in the 11 patients who donated blood for dendritic cell counts.

Sargramostim is a growth factor that helps fight infection and disease in appropriate patients by enhancing immune cell function. It was approved in the United States in 1991, and is marketed by Bayer HealthCare Pharmaceuticals. It is the only growth factor approved in the U.S. for use following induction chemotherapy in older adults (greater than or equal to 55 years) with acute myelogenous leukemia to shorten the time to neutrophil recovery and reduce the incidence of severe and life-threatening and fatal infections.

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