Influence of ML-1 standardized mistletoe extract on the quality of life in head and neck cancer patients.

BACKGROUND: ML-1 standardized mistletoe extracts have been recommended for increasing the health-related quality of life in cancer patients.

PATIENTS AND METHODS: The EORTC questionnaire QLQ-C30((V2)) was given to a randomly chosen subgroup of 399 patients of a prospective, randomized, open, multi-center trial. A total of 200 patients from this trial were randomized for ML-1 treatment (1 ng/kg body weight ML-1 was injected subcutaneously twice weekly over a 60-week period. Treatment cycles of 12 weeks were followed by a break of 4 weeks (between weeks 12-16, 28-32, and 44-48)). The remaining 199 patients formed the control group.

RESULTS: Patients completed questionnaires before the start of their treatments at week 0 and continued until week 156. The compliance rate was high: 3611 questionnaires were available, which equals a median of nine longitudinal measurements per patient between weeks 0 and 156. Analysis did not indicate any improvement in the quality of life for either group. A significant decrease in quality of life, however, was seen in patients undergoing radiotherapy. In these patients, the global state of health was reduced and four symptom scales were significantly worse.

CONCLUSION: Our results demonstrated no improvement in the quality of life in head and neck cancer patients when treated with ML-1 extract.