Impact of complementary mistletoe extract treatment on quality of life in breast, ovarian and non-small cell lung cancer patients. A prospective randomized controlled clinical trial.

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Standardized aqueous mistletoe extracts have been applied to cancer patients for several decades as complementary medicine. A multicentric, randomized, open, prospective clinical trial was conducted in three oncological centers in the People's Republic of China in Bejing, Shenyang and Tianjin. Following the guidelines of "Good Clinical Practice" (GCP) this study was performed to get information on efficacy safety and side-effects of the standardized mistletoe extract (sME). Two hundred and thirty-three patients with breast (n=68), ovarian (n=71) and non-small cell lung cancer (NSCLC; n=94) were enrolled into this study. Two hundred and twenty-four patients fulfilled the requirements for final analysis (n=115 treated with sME HELIXOR A; n=109 comprising the control group being treated with the approved immunomodulating phytopharmacon Lentinan). All patients were provided with standard tumor-destructive treatment schedules and complementarily treated with sME or Lentinan during chemotherapy according to treatment protocol. Biometrically, the patients of the control and sME treatment group were comparable regarding distribution, clinical classification (WHO) and treatment protocols. Analysis was performed according to the "Intention to treat principle". Quality of life (QoL) was significantly ($p<0.05$) improved for patients who were complementarily treated with sME, as determined by the questionnaires FLIC (Functional Living Index-Cancer), TCM (Traditional Chinese Medicine Index) and the KPI (Karnofsky Performance Index) in comparison to the control group. Additionally, the occurrence of adverse events (AEs) was less frequent in the sME than in the control group (total number of AEs 52 versus 90 and number of serious AEs 5 versus 10 in study and control group, most of them due to chemotherapy). Only one serious AE was allocated to complementary treatment in each group (1 angioedema in sME group). All other side-effects of the sME (7 harmless local inflammatory reactions at subcutaneous injection site, 4 cases with fever) were self-limiting and did not demand therapeutic intervention. This study showed that complementary treatment with sME can beneficially reduce the side-effects of chemotherapy in cancer patients and thus improve quality of life.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 15015612 [PubMed - indexed for MEDLINE]