

Homeopathy in treating menopausal symptoms in surgically resected breast cancer patients: a randomized phase II-III trial

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BACKGROUND

Menopausal symptoms significantly impact quality of life in young women with breast cancer history and common substitute hormonal therapies are strongly contraindicated in these patients.

MATERIALS AND METHODS

Trial was conducted in two phases:

Phase II: Pilot phase II study enrolled 10 patients to assume homeopathic treatment Klimaktopant DHU (1 cap, dosage 0,25 g containing Cimicifuga D2 25mg, Sepia D2 25mg, Ignatia D3 25mg, Sanguinaria D2 25mg), sub-lingual, days 1-90.

Phase III: Randomized phase III trial to compare sub-lingual homeopathic treatment versus placebo for 6 months. 35 patients have been enrolled and 31 of them completed the course.

Menopausal symptoms (including but not limited to hot flushes, sweat, insomnia etc) have been evaluated using NCI-CTC scale at two time points: time 0 (basal visit) and time 1 (after 3 months treatments) for patients already enrolled in phase II study, or after 3 and 6 months therapy respectively for newly enrolled patients.

Main objective was to evaluate efficacy and tolerability of a complex homeopathic schedule in the treatment of menopausal symptoms in surgically resected breast cancer patients.

RESULTS

- Phase II: 78 different symptoms have been recorded for whom 57 reductions of at least 1 point score (73%), 17 stability (21.8%), 4 increase of at least 1 point score (5.2%) have been obtained. All symptom scores have been summed up to obtain a single global score per patient per time point. A significant reduction in symptoms and a statistically significant reduction in scores have been observed for all patients (paired data t test, $p < 0,001$);
- Phase III: A significant reduction in global score at time 1 versus time 0 has been observed in patients receiving homeopathic treatment (Wilcoxon Signed Rank test, $p=0,0185$).

CONCLUSIONS

Results obtained from this phase II/III trial have demonstrated efficacy and safety of homeopathic treatment in the cure of menopausal symptoms in a subset of patients that could have not benefited of substitute hormonal therapies.