BP-C1 in treatment of metastatic breast cancer: A randomised, double blinded and placebo controlled clinical study

Aim: The aim was to compare the efficacy and tolerability of a new benzene-poly-carboxylic acids complex with cis-diammineplatinum (II) (BP-C1) versus equal looking placebo in treatment of metastatic breast cancer patients.

Material & Methods: A randomized, double blind, placebo controlled multi-center study was performed with semi-cross-over design. Patients allocated to placebo switches to BP-C1 after 32 days of treatment. Thirty patients were given daily intramuscular injection of 0.035 mg/kg bw BP-C1 or placebo in 32 days. Biochemistry, hematology, NCI Bethesda (CTC-NCI), EORTC QOL-C30 & BR23 recorded at screening and after every 16 days of treatment. CT performed at screening and every 32nd day.

Results: The sum of target lesions increased 2.4% in the BP-C1 group and 14.3% in placebo. The increase in the placebo group was significant (p=0.013) but not in BP-C1. The difference between the group was significant in favor of BP-C1 (p=0.04). Significant difference (p=0.026) in favor of BP-C1 regarding RECIST classification. CTC-NCI toxicity score increased nonsignificantly in the BP-C1 group, but significantly in placebo (p=0.05). “Breast cancer related pain and discomfort” and “Breast cancer treatment problem last week” were significantly reduced (p=0.02) in the BP-C1 group and slightly increased in placebo. Significant difference in favor of BP-C1 (p=0.05). “Breast cancer treatment problem last week” was significantly reduced in the BP-C1 group (p=0.02) and slightly increased in placebo. “Breast cancer related pain and discomfort”.

Conclusion: BP-C1 reduces the cancer growth, is well tolerated, improves quality-of-life and has few mainly mild AE in patients suffering from stage IV MBC.

Biography

Stig Larsen has completed his DSc in Clinical Research Methodology at Ullevål Hospital, Oslo University, Norway. He is Professor at the Norwegian University of Life Science and has published more than 300 papers in international medical and clinical research methodological journals.

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