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### Anti-tumor activity of Wei-Shen: Pre-Clinical and clinical studies

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**Background:** Gastric cancer (GC) is the second leading cause of cancer deaths worldwide. China accounts for over 40% of all new GC cases in the world. Currently the overall 5 year relative survival rate of GC remains poor. New approaches to treat gastric cancer are needed. Wei-shen, a complex prescription based on the theory of Traditional Chinese Medicine (TCM), has shown significant efficacy on GC patients in private practices. In this report, the anti-tumor activity of Wei-Shen was evaluated in both pre-clinical and clinical studies.

**Methods:** A prospective, open label observational study was conducted to investigate the effectiveness of Wei-Shen on gastric cancer patients. The drug was administered in capsules containing 3g raw powder of Wei-Shen BID for 3 to 6 months. The cytotoxicity study was conducted using a serial of dilutions of ethanol extract of Wei-Shen powder on the cultured KATO III gastric, HT29 and HCT15 colorectal and PC-9 lung cancer cells.

**Results:** Total of 38 GC patients were enrolled in the study and treated with Wei-Shen for 3 to 6 months. Among them, complete remission was achieved in 30 patients, whose tumors disappeared in biopsy tests. Some GC patients have disease free survival for over 10 years after being treated Wei-Shen for 3 to 21 months. The treatment of 95% ethanol extract of Wei-Shen for 24-96 hr had dose-dependent anti proliferative or killing effects on cultured KATO III gastric cancer cells. The Wei-Shen extract had similar anticancer effects on HT29 and HCT15 colorectal, and PC9 lung cancer cells.

**Conclusion:** Traditional Chinese Medicine holds great potential to improve people's health and wellness. Wei-Shen demonstrated potent efficacy in gastric cancer patients and complete remission was achieved in subset of patients. Wei-Shen has dramatic cytotoxicity on highly malignant gastric cancer, colorectal and lung cancer cell lines. Further research is needed to elucidate the mechanisms of Wei-Shen's anti-cancer effect. The efficacy and safety of Wei-Shen need to be further investigated in large-scale, placebo-controlled clinical trials.

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