A study on the efficacy and safety assessment of propionyl-L-carnitine tablets in treatment of intermittent claudication.


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OBJECTIVE: This study investigated the efficacy, safety and tolerability of propionyl-L-carnitine (PLC) in patients with intermittent claudication in the Chinese population.

METHODS: In this randomized, multicentre, phase III, double-blind, parallel-group study, 239 patients were randomized to receive PLC 2g/day orally or placebo for 4 months (120 vs. 119). The primary efficacy endpoint was the improvement of peak walking time (PWT) after treatment over baseline, and the secondary endpoints were the improvement of claudication onset time (CT) and ankle/brachial index (ABI).

RESULTS: In the Per Protocol Set (PPS), PWT of the intervention group increased 1.6±1.6 minutes after treatment (p<0.05). With PLC treatment, CT was significantly decreased in the treatment group. ABI was increased in both treatment and control groups. However, no statistical significance was found. In the Safety Analysis Set (SS), there were 110 adverse events during the course of the study (67 in PLC group vs. 43 in control group). There were two serious adverse events in the PLC group and four in the placebo group. All of the SAEs were assessed as unrelated to the study drug which indicated that PLC was well-tolerated in PAD patients.

CONCLUSION: The study showed PLC significantly prolonged the maximum walking time and walking distance of Chinese patients with peripheral arterial disease with well-tolerated performance.

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