Safety assessment of tocotrienol supplementation in subjects with metabolic syndrome: a randomised control trial

ABSTRACT

Previous studies have reported that tocotrienols (T3) possess many distinct properties such as antioxidant, cardioprotective, neuroprotective, anti-cancer, anti-inflammatory and anti-angiogenic, which are beneficial for the improvement of human health. However, there is limited data available on the safety assessment of T3 compared to tocopherols (T). A randomised, double-blinded, cross-over and placebo-controlled human clinical trial was conducted to determine the safety and tolerance of T3 supplementation in 31 subjects with metabolic syndrome. The subjects were supplemented with tocotrienol-rich fraction (TRF) 200 mg or placebo capsules twice daily for two weeks followed by a post-intervention visit. Results showed that T3 supplementation had no significant adverse effect on the red blood cell (RBC), white blood cell (WBC) and platelet counts between TRF (5.10 ± 0.78 × 1012 litre-1, 7.35 ± 1.59 × 109 litre-1, 279.45 ± 73.86 × 109 litre-1, respectively) and placebo interventions (5.13 ± 0.76 × 1012 litre-1, 7.25 ± 1.95 × 109 litre-1, 267.45 ± 68.72 × 109 litre-1, respectively). Measures of serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT)) and albumin did not differ between TRF (25.68 ± 10.72 IU litre-1, 38.26 ± 24.74 IU litre-1, 43.61 ± 2.26 g litre-1, respectively) and placebo interventions (27.39 ± 16.44 IU litre-1, 42.23 ± 33.58 IU litre-1, 43.68 ± 2.15 g litre-1, respectively). This study indicated that supplementation with T3 at the dosage of 400 mg per day for 14 days did not induce haematoxicity and hepatotoxicity in subjects with metabolic syndrome.

Keyword: Metabolic syndrome; Safety; Tocotrienol; Vitamin E