

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 ($5.10 \pm 0.78 \times 10^{12}$ litre⁻¹, $7.35 \pm 1.59 \times 10^9$ litre⁻¹, $279.45 \pm 73.86 \times 10^9$ litre⁻¹, respectively) and placebo interventions ($5.13 \pm 0.76 \times 10^{12}$ litre⁻¹, $7.25 \pm 1.95 \times 10^9$ litre⁻¹, $267.45 \pm 68.72 \times 10^9$ 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 haematotoxicity and hepatotoxicity in subjects with metabolic syndrome.

Keyword: Metabolic syndrome; Safety; Tocotrienol; Vitamin E