A pilot randomised placebo-controlled crossover trial of medicinal cannabis in adolescents with Tourette Syndrome

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Introduction

Medicinal cannabis (MC) has potential therapeutic effects in Tourette Syndrome (TS). The primary aim of this study was to investigate the feasibility of conducting a clinical trial of MC in adolescents with TS. Secondary aims were to assess for safety and to explore for a signal of efficacy.

Methods

This was a phase I/II double-blind, cross-over pilot study comparing MC with matched placebo in adolescents aged 12 to 18 years with TS. The active medication was peppermint-flavoured MCT oil containing THC 10mg/ml and CBD 15mg/ml (Cann Group Limited). The dose titration schedule was stratified into two participant weight bands: below 50kg (max THC 10mg/d) or ≥ 50kg (max THC 20mg/d). Each treatment phase lasted 10 weeks, with a four-week washout period.

Results

Ten children were randomised (mean age 14.8, 50% male), and seven completed the full study protocol. Two discontinued due to adverse events (one on MC, one placebo), and one was lost to follow-up. There were no serious adverse events. Protocol adherence was excellent: study visits 100%, blood test completions 100%, online questionnaire completion 97.6%. Medication adherence was acceptable in 61.5%. Parents reported a high degree of study design acceptability. On the Clinical Global Impression – Improvement scale three participants were rated as much improved on MC compared to one on placebo.

Discussion

The findings suggest that the study protocol is feasible and acceptable to patients with TS and their families. The study drug was well-tolerated. There was an efficacy signal in favour of active drug. A larger study is needed.

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Cann group