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SAFETY OF A CANNABIS-BASED OIL FOR PATIENTS WITH MULTIPLE MYELOMA UNDERGOING AUTOLOGOUS STEM CELL TRANSPLANTATION: PROTOCOL OF A PHASE I/II STUDY

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Educação e Pesquisa

INTRODUCTION

Autologous stem cell transplantation (ASCT) is associated with symptoms that impact quality of life of patients living with multiple myeloma (MM). Cannabis products are used to mitigate adverse events related to cancer, yet safety data regarding its use among patients receiving high-intensity chemotherapy are not available. Currently under Brazilian regulation, cannabis-based products are allowed to be commercialized as THC concentrations do not exceed 0.2%.

AIM

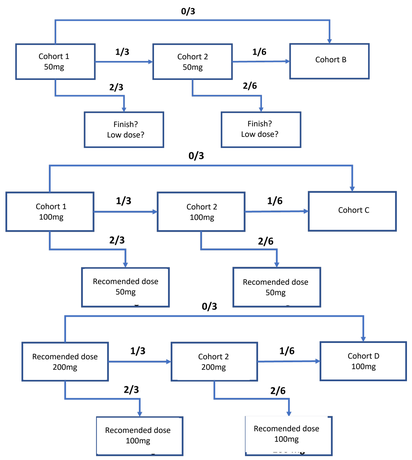
Establish the safety and maximal tolerated dose of cannabidiol for patients with MM undergoing ASCT. Access the capacity of a cannabis-based product to reduce the burden of symptoms related to the administration of myeloablative chemotherapy.

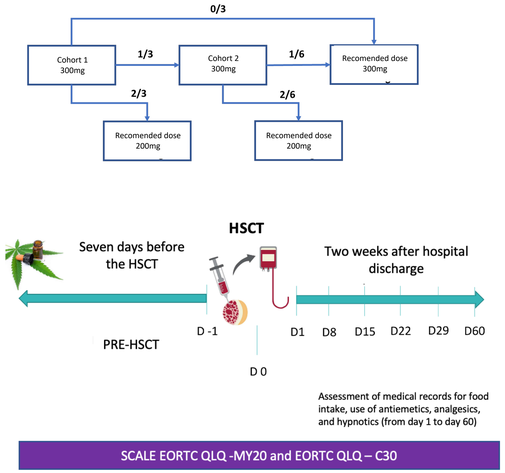
METHOD

Study Design, Intervention, and Sample Size: This is a phase I/II clinical trial of *Cannabis* stratum 160.3 mg/mL (CBD 90 mg/mL, THC 2.3 mg/mL). During phase I, we will follow a 3+3 design to access the maximal dose. The target dose for each cohort will be 50 mg for cohort A, 100 mg for cohort B, 200 mg for cohort C, and 300 mg for cohort D. The stratum will begin 7 days prior to ASCT admission and conclude 15 days after hospital discharge. At phase II, the maximum tolerated dose will be administered to 15 patients to gauge the treatment efficacy. The study will enroll ≤39 patients.

METHODS

Inclusion Criteria: Adult patients with MM, candidates for ASCT.
Exclusion criteria: Allergy to any component of the intervention, incapacity to fill the study's surveys, use of valproate or clobazam, prior episode of mania, prior admission to a psychiatric ward, current use of antipsychotic medication, and history of substance abuse for the last 5 years.
Primary Outcome: Dose-limiting toxicities (hepatotoxicity, psychotropic effects or "high," hallucinations or delirium, psychosis and paranoia, agitation, major depressive episode, mania or hypomania, incapacity to reach target dose).
Secondary Outcomes: Quality of life (accessed with EORTC QLQ-30 and EORTC MY-20), body weight and albumin levels, dietary intake (by a dietitian), highest-grade mucositis, requirement of antiemetics, requirement of painkillers, hospital discharge, neutrophilic and platelet engraftment, admissions to the ICU, febrile neutropenia, and infections





CONCLUSIONS

The study started accruing patients in June 2024.

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