Poster: TIP-002

Title: Study design of a phase 1 single-center, open-label, three-period, fixed sequence study of cannabidiol and tacrolimus

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**Supplement**

**Figure S1**

A screenshot of a computer

Description automatically generated

**Cell culture schema.** On Day 1, whole blood (10 mL) was collected into an EDTA-containing tube, which is fractionated to obtain PBMCs in the buffy coat. Sample was incubated with PHA to isolate lymphocytes. On Day 2, lymphocytes were exposed to three treatment conditions in two sets of apparatus: 96-well plate and T25 flask. Both were incubated for 48 hours. On Day 4, CellTiter-Glo was added to the 96-well plate and read under a plate reader to quantify cell proliferation. The lymphocytes in T25 flask underwent single-cell RNA sequencing. EDTA, ethylenediaminetetraacetic acid; PBMC, peripheral blood mononuclear cell; PHA; phytohemagglutinin; RPMI, Roswell Park Memorial Institute.

**Table S1**

**Study calendar for subjects to follow.**

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| --- | --- | --- |
| **Period 1** | | |
| Day 1  **Inpatient ICRC**  **Tacrolimus 5 mg x1**  -Blood and urine collections  -High-calorie and high-fat diet  -Estimated length: 12 hours | Day 2  **Outpatient ICRC**  -Blood and urine collections  -Estimated length: 30 min | Day 3  **Outpatient ICRC**  -Blood collection  -Estimated length: 30 min |
| **Wash-out period** | | |
| **Period 2** | | |
| Day 8\*  **Inpatient ICRC**  **Cannabidiol 5 mg/kg x1**  -Blood and urine collections  -High-calorie and high-fat diet  -Estimated length: 12 hours | Day 10  **Outpatient ICRC**  -Blood and urine collections  -Estimated length: 30 min | Day 12  **Outpatient ICRC**  **Cannabidiol 2.5 mg/kg twice daily (administer the first dose under supervision at ICRC)**  -Blood and urine collections  -Estimated length: 1 hour |
| **Period 3** | | |
| **Cannabidiol steady-state titration period**  Day 12-14: take cannabidiol 2.5 mg/kg twice daily  Day 15-23: take cannabidiol 5 mg/kg twice daily | | |
| Day 24\*  **Inpatient ICRC**  **Cannabidiol 5 mg/kg twice daily**  **Tacrolimus 5 mg x1**  -Blood and urine collections  -High-calorie and high-fat diet  -Estimated length: 12 hours | Day 25  **Outpatient ICRC**  **Cannabidiol 5 mg/kg twice daily**  -Blood and urine collections  -Estimated length: 30 min | Day 26  **Outpatient ICRC**  **Cannabidiol 5 mg/kg twice daily**  -Blood and urine collections  -Estimated length: 30 min |
| \*Minor rescheduling of visits is allowed, and subsequent visits would be adjusted accordingly | | |

ICRC, Indiana Clinical Research Center (ICRC).