Treatment of Chronic Pain with Cannabidiol (CBD) and Tetrahydrocannabinol (THC)

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Time Line of Regulatory Approvals

- IND Approval: September 6th, 2017
- IRB Approval: September 18th, 2017
- Certificate of Confidentiality Approval: October 3rd, 2017
- Schedule I Registration Approval: January 12th, 2018
- Study Drug Received: January 11th, 2019
- IRB Post IND Compliance Audit: May 9th, 2019
Study Design

Screen

Day 1 (Monday)
Baseline
Day 2
Day 3
Day 4
Day 5
Follow-up
Day 7 (Monday)

Bio-specimens
fMRI & MRS Scans
Testing
Recruitment Approaches

**Efforts**

- [Clinicaltrials.gov](#): 171 Inquires, 32 Phone Screened
- Advertising (Fliers & Radio): 16 Inquires, 10 Phone Screened

- **Start:** 5/1/19
- **Enrolled:** 8
- **15 in Screening**

*We want you!*
Reasons for Ineligibility

Cannabis naive
Traumatic Brain Injury
Medical Condition
Disqualifying Pain
Distance
Not Interested
Opioid Use Factors

**NEED HIGHER DOSE**
- Never: 28%
- Seldom: 14%
- Sometimes: 29%
- Often: 29%

**IMPATIENT WITH DOCTOR**
- Never: 29%
- Sometimes: 57%
- Seldom: 14%
Pain Characteristics

- Average Pain Rating At 1st dosing visit = 4.1
- Worst Pain on over past 24 hours = 4.5
- Lowest Pain over past 24 hours = 2.3
- Average Duration of Pain in months = 90 (7.5yrs)
  - Range = 12 – 204 months (1 -17 yrs)
- Common Locations
  - Low Back
  - Hips & SI joints
  - Neck
Spectroscopy Methods

1H MRS Focused on Anterior Cingulate Cortex (ACC)

• Two types of 1H MRS measurements performed:

  J-edited 1H MRS (HERMES) for ACC GABA measures

  Two-dimensional (2D) J-resolved 1H MRS for measures of other ACC metabolites including glutamate, glutamine, NAA, myo-inositol, and choline-containing compounds
Stability of Tissue Composition
ACC Metabolite Measures: 2D J-resolved 1H MRS
Assessment of Pressure Algometry

- Assessed Usability of Two Different Pressure Algometers
  - Digital – increasing pressure
  - Manual – steady pressure across time

- Fifty-nine participants
  - Half female, ages 19-70
  - Found that manual algometer is ok for pain threshold, but has a ceiling effect when measuring tolerance
  - Participants tolerate objective pain measures in research protocols
Objective Pain Measurement – Pressure Algometer in MJ Sample

- Average Pre-Dose Pain Threshold = 10.03 (4.25) lbf
  - Range = 4.78 – 19.49 lbf of Pressure
- Average Post-Dose Pain Threshold = 10.57 (5.09) lbf
  - Range = 5.48 – 22.01 lbf of Pressure

- Increase in Pain Threshold Post-Dose