

Clinical Study to Evaluate the Effects of Oral Delta-9-tetrahydrocannabinol (9-THC) With and Without Alcohol on Perception and Driving Performance in Healthy Adults

NCT07176208

Status	RECRUITING
Phase	Phase 1
Sponsor	Food and Drug Administration (FDA)
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (13)

- Subject signs an IRB approved written informed consent and privacy language as per national regulations (e.g., Health Insurance Portability and Accountability Act authorization) before any study related procedures are performed.
- Subject is a healthy, non-smoking man or woman, 21 to 55 years of age, inclusive, who weighs at least 50 kg (110 lbs) and has a body mass index of 18.5 to 33.0 kg/m², inclusive, at Screening and check-in (Day -1).
- Subject possesses a valid U.S. driver's license and has driven a minimum of 600 miles per year for the previous 3 years.
- During screening subjects will be assessed using a driving simulation test. Subject must not demonstrate any motion sickness as determined by the investigator and defined in the driving simulation operations manual and subject must not have erratic driving as defined in the Screening Visit Driving Practice Assessment Operational Manual.
- Subject has normal medical history findings, clinical laboratory results, vital sign measurements, 12-lead ECG results, and physical examination findings at screening and check-ins or, if abnormal, the abnormality is not considered clinically significant (as determined and documented by the investigator or designee). Out of range tests may be repeated once for confirmation at screening and/or check-ins at investigator's discretion.

... and 8 more (see full listing online)

Exclusion (27)

- A history of cannabis use disorder or use of any psychoactive drug in the last month.
- Any reported history of alcohol intolerance.
- Alcohol intolerance as detected by ethanol patch testing.
- Subject has a dry mouth or history of salivary gland dysfunction or surgery.
- A history of any psychiatric diagnosis, including mood, anxiety, and psychotic disorders.

... and 22 more (see full listing online)

Locations (2 total)

Spaulding Clinical Research, West Bend, Wisconsin, United States
Spaulding Clinical, West Bend, Wisconsin, United States

<https://clinicaltrials.gov/study/NCT07176208>

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