HEALTHY SUBJECTS NEEDED FOR A BOTANICAL-DRUG INTERACTION STUDY

This study will help establish the safety or risks of combining botanicals with pharmaceutical drugs.

The purpose of this research study is to determine if the botanical product kratom changes the effects and/or breakdown of a drug of interest. This study will consist of four study arms, lasting at least 5 weeks in total. Each arm will include one inpatient day lasting around 13 hours each. During Arm 1, you will be given a single low dose of kratom tea. During Arm 2, you will be given a single dose of the drug. During Arm 3, you will be given both kratom tea and the drug. During Arm 4, you will drink kratom tea daily at home for 4 days (pre-measured doses and detailed instructions on how to prepare the tea each day will be provided). You will then return to the clinical study site, where you will be given kratom tea and the drug. Your pupil diameter will be measured by the research staff at time intervals throughout the day. Blood will be drawn from an intravenous line during Arms 2, 3, and 4. Urine samples will also be collected during those arms. The inpatient days for Arms 2, 3, and 4 will be followed by an outpatient visit the following morning, when blood will be drawn and pupil diameter will be measured; you will also return your urine jug(s) at this visit. You will receive a screening medical exam and will undergo routine blood and urine laboratory tests, as well as a urine toxicology screen for common drugs of abuse prior to participating in the study.

You will receive

- up to $1,400 for completing the entire study

You may be eligible to take part in this study if you

- are 21-45 years old, weigh between 130 and 250 lbs., and healthy;
- are not taking any medications, dietary/herbal supplements, or fruit juices that can interfere with your ability to eliminate kratom and the study drug;
- are willing to abstain from cannabis/marijuana, hemp, THC, and CBD products for several weeks;
- are willing to abstain from consuming caffeine-containing products and beverages the evening before and the morning of each study day;
- are willing to abstain from consuming any alcoholic beverages for at least 1 day prior to any study day and during the study day;
- are willing to use an additional method of non-hormonal contraception (such as abstinence, copper IUD, condom);
- have consumed kratom and opioids previously and tolerated it well without unpleasant effects and are willing to abstain from taking it for at least two weeks prior to and for the duration of the study; and
- have the time to participate.

You will not be eligible to take part in this study if you

- have a chronic illness or major psychiatric illness;
- have a hematologic (blood) disorder;
- have a history of any substance abuse, addiction, or dependence;
- are pregnant or breastfeeding;
- have a history of intolerance or allergy to kratom or opioid analgesics;
- have a need for chronic opioid analgesics or an imminent likely need for opioid analgesics (e.g., planned dental or surgical procedure);
- have used opioid analgesics 3 weeks prior to initiation of the study;
- have ever used amphetamines, benzodiazepines, cocaine, MDMA, opioids, PCP, or other drugs for recreational purposes;
- have used cannabis/marijuana, hemp, CBD- and/or THC-containing products within the past month;
- are taking concomitant medications, both prescription and non-prescription (including dietary supplements/herbal products), known to alter the pharmacokinetics of either the study drug or kratom; and/or
- are unable to speak, read, and understand English.

The Washington State University College of Pharmacy and Pharmaceutical Sciences is conducting this research study through funding provided by the National Institutes of Health.

For more information about this study, please contact:

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The WSU Institutional Review Board has reviewed and approved this research project for human subject participation.