Biomarkers of Exposure and Effect in SREC Users

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is also accepting healthy volunteers

Inclusion Criteria:

Male or female smokers who are 18-65 years of age and are willing to stop smoking and completely switch to e-cigarettes or medicinal nicotine; Report smoking ≥ 5 cigarettes daily and not using any other nicotine or tobacco product; Biochemically confirmed regular smoking status by a NicAlert test level of 6; Smoking daily for at least 1 year and no serious quit attempts (e.g., quit for 24 hours or longer) in the last 3 months (to ensure stability of daily smoking, particularly for those randomized to the continued smoking group); No unstable and significant medical or psychiatric conditions as determined by medical history and Prime-MD (to ensure safety of the subject, to minimize the effects of poor health on biomarker measures and to maximize compliance to study procedures); Subjects are in good physical health (no unstable medical condition); Subjects are in stable, good mental health (e.g. not currently, within the past 6 months, experiencing unstable or untreated psychiatric diagnosis, including substance abuse); Subjects who are not taking anti-inflammatory medications or any medications that affect relevant metabolic enzymes; Women who are not pregnant or nursing or planning to become pregnant; Subject has provided written informed consent to participate in the study (adolescents under the age of 18 will be excluded because this project involves continued use of tobacco products and new tobacco products).

Exclusion Criteria:

Regular tobacco or nicotine product use (e.g., 9 days in last 30 days) other than cigarettes; Currently using nicotine replacement or other tobacco cessation products; Significant immune system disorders, respiratory diseases, kidney or liver diseases or any other medical disorders that may affect biomarker data; Unstable health conditions (any significant serious, unstable medical condition including, but not limited to, cardiovascular disease, unstable COPD, seizure disorder and cancer, as determined by the licensed medical professional); Unstable mental health (to be determined by medical history, CESD, Prime-MD after review by the licensed medical professional); Excessive drinking (e.g., 5 or more drinks daily) or problems with drinking or drugs (e.g., self-report of binge drinking alcohol or treatment for drug or alcohol abuse within last 3 months); to be assessed by PI or licensed medical professional; Blood alcohol test > 0.01 (g/dL) as measured by a breath sample at screening (participants failing the breath alcohol screen will be allowed to re-screen once; Positive toxicology screen for any of the following drugs: cocaine, opiates, methadone, benzodiazepines, barbiturates, amphetamines, methamphetamines, and PCP. Failing temperature strip for the sample. Marijuana will be tested for, but will not be an exclusionary criterion. Participants with valid prescriptions for opiates, benzodiazepines, barbiturates, amphetamines or methadone will not be excluded. Participants failing the toxicology screen will be allowed to re-screen once; Pregnant or breastfeeding; Failure to agree to take adequate protection to avoid becoming pregnant during the study; Vital signs outside of the following range (participants failing for vital signs will be allowed to re-screen once): Systolic BP greater than or equal to 160 mm/hg Diastolic BP greater than or equal to 100 mm/hg Systolic BP below 90 mm/hg and symptomatic (dizziness, extreme fatigue, difficulty thinking, inability to stand or walk, feeling faint) Diastolic BP below 50 mm/hg and symptomatic (dizziness, extreme fatigue, difficulty thinking, inability to stand or walk, feeling faint) Heart rate greater than or equal to 105 bpm Heart rate lower than 45 bpm and symptomatic (dizziness, extreme fatigue, difficulty thinking, inability to stand or walk, feeling faint) Expired air carbon monoxide (CO) level greater than 80 ppm; Self-reported allergies to propylene glycol or vegetable glycerin; Adverse reactions when previously using electronic cigarettes; Household member enrolled in the study concurrently; Unable to read for comprehension or completion of study documents; Unstable living environment that would compromise the ability to attend visits, sequester study products or complete study procedures outside of visits.

Conditions & Interventions

Interventions:
Drug: Nicotine Mini-Lozenge, Drug: Standardized Research E-cigarette (SREC)
Conditions:
Prevention & Wellness

More Information

Description: The purpose of this study is to better understand how switching from smoking to the use of electronic cigarettes (e-cigarettes) may change users' exposures to various harmful chemicals. Your participation will also help us to understand how nicotine that is present in e-cigarettes is taken in and modified by your body.
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Phase: Phase 1
IRB Number: STUDY00002033