

Nordic Spirit Pouch Nicotine Pharmacokinetics Abuse Liability

NCT07476144

Status	RECRUITING
Phase	Phase 1
Sponsor	JT International SA
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (25)

- Voluntary consent to participate in this study documented on the signed ICF.
- Healthy adult males and females e22 and d65 years of age, at screening.
- Smokers and smokers that use other tobacco products (i.e., snus, moist snuff, Electronic Nicotine Delivery Systems, NP) will be considered. Smoking history (self-reported at screening) of an average of at least 5 but no more than 30 factory-manufactured combustible cigarettes daily for at least 12 months prior to screening. Brief periods (i.e., up to 7 consecutive days) of nonsmoking during the 3 months prior to screening (e.g., due to illness or participation in a study where smoking was prohibited) will be permitted.
- Participants must demonstrate the ability to use a 12-mg NP for 30 minutes.
- Participants who use THC, must be willing to abstain from THC use for 7 days before Check-in and able to participate in the study without THC use.

... and 20 more (see full listing online)

Exclusion (32)

- Self-reported puffers (i.e., adult smokers who draw smoke from the cigarette into the mouth and throat but do not inhale).
- Any postponement of a quit attempt to participate in the study; or any attempts to quit smoking in the 3 months prior to Check-in).
- Poor dentition that prevents participant from using nicotine gum.
- History or presence of any type of malignant tumor or clinically significant gastrointestinal, renal, hepatic, neurologic, hematologic, endocrine, oncologic, urologic, pulmonary, immunologic, psychiatric, or cardiovascular disease, or any other condition that, in the opinion of the Investigator, would interfere with the absorption, distribution, metabolism, or excretion of nicotine or jeopardize the safety of the participant or impact the validity of the study results.
- Current evidence or any history of congestive heart failure.

... and 27 more (see full listing online)

Locations (2 total)

AMR, Knoxville, Tennessee, United States
ICON San Antonio, San Antonio, Texas, United States

<https://clinicaltrials.gov/study/NCT07476144>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).