

Nicotine Replacement Therapy, Counseling, Varenicline, and Bupropion for Smoking Cessation, the PISCES I Trial

NCT04604509

Status	RECRUITING
Phase	Phase 4
Sponsor	M.D. Anderson Cancer Center
Enrollment	2,010 participants

Key Eligibility Criteria

Inclusion (9)

- Smoking 5 or more cigarettes, little cigars and/or cigarillos per day, on average, within the past 30 days preceding the screening visit and expired carbon monoxide (CO) \leq 6 ppm and/or a urine Nic Check test \geq 0 (or a reading of positive if an alternate nicotine test used)
 - Interested in treatment that might change smoking behavior or help them quit smoking
 - Able to follow verbal and written instructions in English and complete all aspects of the study
 - Provide informed consent and agree to all assessments and study procedures
 - Have an address and telephone number where they may be reached
- ... and 4 more (see full listing online)

Exclusion (15)

- Current enrollment or plans to enroll in another smoking cessation program during the study time frame, including plans to use other smoking cessation medications (i.e., over the counter [OTC] or prescription medication for smoking cessation) or smoking cessation treatments
 - Serious or unstable medical or psychiatric disorder within the past 3 months, as determined by the study physician
 - Being pregnant, engaging in breast-feeding, or being of childbearing potential and engaging in sexual activity that could lead to pregnancy and is not protected by a medically acceptable, effective method of birth control while enrolled in the study, as determined by self-report. Medically acceptable contraceptives include: (1) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (2) barrier methods (such as a condom or diaphragm) used with a spermicide, or (3) an intrauterine device (IUD). Contraceptive measures sold for emergency use after unprotected sex are not acceptable methods for routine use
 - Current use of certain medications:
 - Smoking cessation meds (last 7 days; e.g., bupropion, NRT, varenicline). Episodic use of NRT in the last 7 days may be considered if the participant agrees to only use study medication once randomized
- ... and 10 more (see full listing online)

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT04604509>

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. Generated by ClinicalTrialsFinder.org.