

Inclusion and Exclusion Criteria and Assessment of Eligibility

Inclusion Criteria

Subjects must be 18-65 years old, have smoked an average of at least 10 cigarettes per day for one cumulative year, have an expired air CO reading assessed at screening of at least 10 ppm, and express a desire to quit smoking within the next 30 days.

Exclusion Criteria

- Hypertension (systolic >140 mmHg, diastolic >100 mmHg, coupled with a history of hypertension); subjects with no previous diagnosis of hypertension may have a screening blood pressure up to 160/100.
- Hypotension with symptoms (systolic <90 mmHg, diastolic <60 mmHg).
- Participants with a history of hypertension may, however, be allowed to participate in the study if the study physician or physician assistant determines that the condition is stable, controlled by medication, and in no way jeopardizes the individual's safety.
- Coronary heart disease;
- Lifetime history of heart attack;
- Cardiac rhythm disorder (irregular heart rhythm);
- Chest pains (unless history, exam, and ECG clearly indicate a non-cardiac source);
- Cardiac (heart) disorder (including but not limited to valvular heart disease, heart murmur, heart failure);
- History of skin allergy;
- Active skin disorder (e.g., psoriasis) within the last five years, except minor skin conditions (including but not limited to facial acne, minor localized infections, and superficial minor wounds);
- Liver or kidney disorder (except kidney stones, gallstones);
- Gastrointestinal problems or disease other than gastroesophageal reflux or heartburn;
- Active ulcers in the past 30 days;
- Currently symptomatic lung disorder/disease (including but not limited to COPD, emphysema, and asthma);
- Brain abnormality (including but not limited to stroke, brain tumor, and seizure disorder);
- Migraine headaches that occur more frequently than once per week;
- Recent, unexplained fainting spells;
- Problems giving blood samples;
- Diabetes treated with insulin; non-insulin treated diabetes (unless glucose is less than 180 mg/dL and HbA_{1c} is less than 7%);
- Current cancer or treatment for cancer in the past six months (except basal or squamous cell skin cancer);
- Other major medical condition;
- Current psychiatric disease (with the exception of anxiety disorders, OCD and ADHD);
- Suicidal ideation (within the past 10 years) or lifetime occurrence of attempted suicide;

- Current depression - The Patient Health Questionnaire PHQ-9 for Depression will be used to screen for current (within 2 weeks) depression. Potential subjects who score >9 (or who score >0 on item 9 (“Thoughts that you would be better off dead, or of hurting yourself in some way”)) will be excluded from study participation, and, at the discretion of the study physician, referred to appropriate psychiatric treatment;
- Bulimia or anorexia;
- Pregnant or nursing mothers;
- Use (within the past 30 days) of:
 - Illegal drugs (or if the urine drug screen is positive for THC, cocaine, amphetamine, opiates, methamphetamines, PCP, benzodiazepines, or barbiturates),
 - Experimental (investigational) drugs;
 - Psychiatric medications including antidepressants, anti-psychotics or any other medications that are known to affect smoking cessation (e.g. clonidine);
 - Smokeless tobacco (chewing tobacco, snuff), pipes or e-cigarettes;
 - Wellbutrin, bupropion, Zyban, Chantix, nicotine replacement therapy or any other smoking cessation aid.
- Use of opiate medications for pain or sleep (non-opiate medication for pain or sleep will be allowed) within the past 14 days;
- Smokes more than one cigar a month.
- Alcohol abuse - The AUDIT (Alcohol Use Disorders Identification Test) questionnaire will be used to assess alcohol abuse. Potential participants will be asked the first two questions on the AUDIT questionnaire during the phone screen. If the person scores 4 on both questions, a screening appointment will not be scheduled. During the screening session the entire AUDIT questionnaire will be administered. Females who score greater than or equal to 13 and males who score greater than or equal to 15 will be excluded from the study.
- Significant adverse reaction to nicotine patches, nicotine inhalers, bupropion/Wellbutrin/Zyban or Chantix/varenicline in the past.
- Current participation or recent participation (in the past 30 days) in another smoking study at our center or another research facility.
- Current participation in another research study.

Assessment of Eligibility

Potential subjects who do not have a self-reported diagnosis of the above listed conditions may be excluded if the study physician or physician assistant determines that the history, physical findings, ECG, or laboratory studies reveal information that may jeopardize the subjects’ safe study participation. For medical conditions that do not appear above, the study physician will be consulted and if the medical condition does not jeopardize safe study participation, then the subject may be enrolled.