Study of Nicotine for Pain Associated With Chemotherapy-Induced Peripheral Neuropathy

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Clinically diagnosed peripheral sensory neuropathy defined as:

• Greater than Grade 1 peripheral sensory neuropathy using the CTCAE v5.0 grading scale

• Grade 1 Asymptomatic

• Grade 2 Moderate symptoms; limiting instrumental activities of daily living (ADL)

• Grade 3 Severe symptoms; limiting self-care ADL

• Grade 4 Life-threatening consequences; urgent intervention indicated

• Have a baseline CIPN PRO total sensory score ≥ 24.3 on a 19 to 76 scale using the EORTC QLQ-CIPN-20 questionnaire

• Have a CIPN-related neuropathic pain score ≥ 4 on a 0 to 10 scale using the Brief Pain Inventory-Short Form (BPI-SF) item 5

• Will not have used any nicotine or tobacco products (eg, cigarettes, electronic cigarettes, smokeless tobacco, or other nicotine replacement therapies) within 14 days prior to study treatment start date

• Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2

• Not currently receiving any chemotherapy

• Have previously received platinum- and/or taxane-based chemotherapy treatments and have persistent pain at least 3 months after completion of treatments.

• Willing and able to comply with study procedures and visit schedule.

• Willing to abstain from all tobacco/nicotine product use during study treatment and 30-day follow-up period.

• Ability to self-apply or have the patch applied at home daily.

• Ability to understand and the willingness to sign a written informed consent document

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Exclusion Criteria:

• History of pre-existing peripheral sensory neuropathies related to the following:

• Autoimmune disease

• B12/folate deficiency

• Diabetes Mellitus

• Human immunodeficiency virus (HIV)

• Hyper/hypothyroidism

• Monoclonal gammopathy of undetermined significance or multiple myeloma

• History of receiving other types of neurotoxic chemotherapy drugs (eg, vinca alkaloids, bortezomib, thalidomide)

• Current or prior pheochromocytoma

• History of or active or clinically significant cardiac disease including any of the following:

• Unstable angina (eg, anginal symptoms at rest) or onset of angina within 3 months prior to initiating study treatment

• Myocardial infarction diagnosed within 6 months prior to initiating study treatment

• Cardiac arrhythmias requiring anti-arrhythmic therapy other than beta blockers

• New York Heart Association (NYHA) class III or IV congestive heart failure

• Poorly controlled high or low blood pressure defined as:

• SBP ≥ 140; DBP ≥ 90

• SBP ≤ 90; DBP ≤ 60

• Regular use of the following medications:

• Varenicline

• Bupropion (ie, bupropion hydrochloride sustained release)

• Women will be excluded if they are breastfeeding or are pregnant (by urinalysis) within 14 days prior to the start of nicotine transdermal patch administration.

• Medical, psychological, or social condition that, in the opinion of the investigator, may increase the patient's risk or limit the patient's adherence with study requirements

Conditions & Interventions

Interventions:
Drug: Nicotine Transdermal Patch
Conditions:
Neuropathy, Peripheral Neuropathy, Neuropathic Pain, Chemotherapy-induced Peripheral Neuropathy
Keywords:
Nicotine, Peripheral Neuropathy

More Information

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Phase: Phase 2

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