A randomized phase II clinical trial of acupuncture for preventing taxane-induced peripheral neuropathy in patients with early-stage breast cancer

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Abstract

The ATP trial is a two-arm, parallel, randomized controlled trial comparing weekly real acupuncture (RA) versus sham acupuncture (SA) during preplanned curative intent taxane containing regimens in patients with breast cancer. The study will include two phases: screening and intervention. In the screening phase, eligible patients will consent and receive CIPN screening each week. The primary aim is to measure neuropathic pain progression using the Neuropathic Pain Scale (NPS). The secondary aim is to evaluate chemotherapy dose intensity and chemotherapy induced neuropathy-related discontinuation rates. ClinicalTrials.gov Identifier: NCT05458284

Introduction

Chemotherapy-induced peripheral neuropathy (CIPN) is a common, debilitating and dose-limiting side effect from many chemotherapy agents. Patients with CIPN often experience neuropathy symptoms such as pain, tingling, and numbness which can be detrimental to cancer survival, increasing the risk of falls and worsening physical functions.

There is currently no effective treatment or preventative measure for CIPN. Many patients with CIPN require dose reduction or discontinuation of chemotherapy, with potentially detrimental effects on survival. Effective CIPN preventative measures are urgently needed.

Acupuncture is a minimally invasive, traditional Chinese medicine technique that has shown promising evidence as an effective and safe treatment for CIPN. We hypothesize that acupuncture may retard CIPN progression and lead to better quality of life and optimize chemotherapy delivery for early-stage breast cancer patients.

Specific Aims

The primary aim is to evaluate the effectiveness of RA versus SA in preventing taxane-induced peripheral neuropathy progression as measured by Neuropathic Pain Scale (NPS) in patients with early-stage breast cancer who are receiving curative intent neurotoxic chemotherapy.

The secondary aim is to evaluate the effectiveness of RA versus SA on chemotherapy relative dose intensity (RDI) and CIPN-related chemotherapy discontinuation.

Eligibility

Key Eligibility criteria for the screening phase:
- English or Spanish proficient
- Age ≥18 years
- Histological diagnoses of invasive carcinoma of the breast
- Plan to receive curative intent chemotherapy regimen containing paclitaxel or nab-paclitaxel weekly or biweekly as standard of care.

Key Eligibility criteria for the intervention phase:
- Developed CIPN grade ≥1 based on the NCI-CTCAE version 5.0, while receiving taxane
- ≥ four weeks of paclitaxel or nab-paclitaxel weekly or biweekly planned, as standard of care and at treating physician’s discretion
- Willing to adhere to requirement that no new pain medication or dose changes be taken throughout the first 12 weeks of the study period

Study Design

We will randomize 80 patients, 40 to each arm. All randomized patients will be evaluable in the Intent to Treat (ITT) analyses because all will have completed the baseline assessment before randomisation.

We will use a linear mixed model (LMM) to compare the change in NPS between the arms from baseline to week 4. With 80 patients we will have 80% power to detect a difference between arms as small as 10 points on the NPS, assuming a one-sided test, type I error of 5%, correlation between baseline and follow-up measurements of 0.5, SD of 17, and 15% attrition at week 4.

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