Scalp Cooling Alopecia Prevention Trial (SCALP) for Patients with Early Stage Breast Cancer

Julie R. Nangia[1], Tao Wang[1], Mari Rude[1], Frankie Ann Holmes[2], Cynthia Osborne[2], Steven W. Papish[2], Richard Paxman[3], Susan G. Hilsenbeck[1], C. Kent Osborne[1], Mothaffar Rimawi[1]

[1]Baylor College of Medicine, [2]US Oncology, [3]Paxman Coolers LTD

Baylor College of Medicine

LESTER & SUE SMITH BREAST CENTER

Background

Adjuvant chemotherapy treats micro-metastatic disease and decreases the risk of breast cancer recurrence. However, it may be associated with distressing adverse effects, including alopecia. Women with breast cancer rate chemotherapy-induced alopecia as one of the most severe, troublesome, and distressing side effects of chemotherapy. In many countries, scalp cooling has been introduced to prevent or reduce chemotherapy-induced alopecia. Scalp cooling causes cutaneous vasoconstriction, which reduces blood flow to the hair follicles during peak plasma concentrations of the chemotherapeutic agents and therefore reduces cellular uptake of these agents. It also results in reduced biochemical activity, which makes hair follicles less susceptible to the damage of the chemotherapy agents. Success rates are variable, but scalp cooling appears to be effective in preventing chemotherapy-induced alopecia especially in more recent studies.

Purpose

To demonstrate that the Orbis Paxman Hair Loss Prevention System is safe and effective in reducing chemotherapy-induced alopecia in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy.

Study Hypothesis

- The Orbis Paxman Hair Loss Prevention System will significantly reduce chemotherapy-induced alopecia in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy
- Women who do not have clinically significant alopecia will have a better quality of life compared to those with alopecia and that the reduction of alopecia in breast cancer patients undergoing chemotherapy is associated with a lower risk of depression
- Scalp cooling using the Orbis Paxman Hair Loss Prevention System is not associated with any unanticipated, clinically significant short-term safety effects, and the scalp cooling procedure is well-tolerated by patients undergoing chemotherapy
- Scalp cooling using the Orbis Paxman Hair Loss Prevention System does not present an increased risk of scalp metastases for patients newly diagnosed with stage I – II breast cancer

Primary Endpoints

Efficacy: To compare success in hair preservation, between the Orbis Paxman Hair Loss Prevention System and control (no cooling) after 4 cycles of chemotherapy.

Safety: To estimate the rate of significant cold-related anticipated device events

Secondary Endpoints

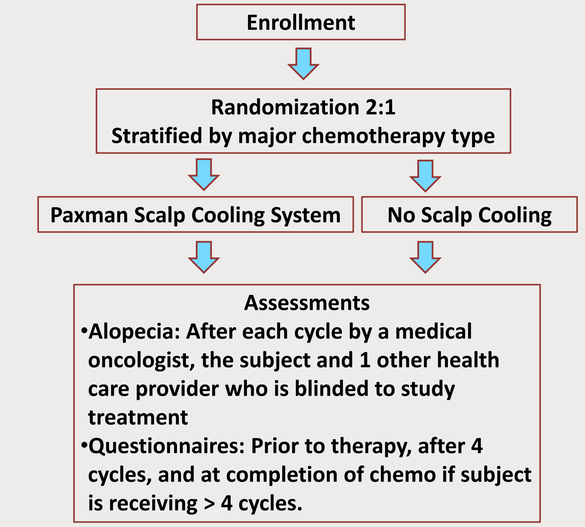
Efficacy: To compare the 2 groups on the basis of patient-perceived hair preservation), medical oncologist-perceived hair preservation, rate of use of wigs or head wraps, and change in quality of life (EORTC QLQ-30, Hospital Anxiety & Depression Scale, and Body Image Scale questionnaires)

Safety: To compare the 2 groups on the basis of patient reported comfort, rate of early scalp metastases and survival.

Eligibility

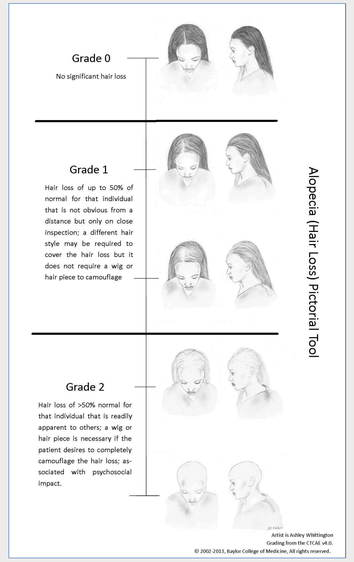
- New diagnosis of breast cancer stage 1-2
- Planning to undergo neoadjuvant or adjuvant chemotherapy with curative intent
- Chemotherapy must be planned for at least 4 cycles of full-dose anthracycline or taxane based chemotherapy regimen
- No prior chemotherapy
- No migraines, hypothyroidism, hepatitis, uncontrolled DM, underweight subjects or anemia
- No Lichen planus or lupus

Schema



Clinicaltrials.gov: NCT01986140

Alopecia Grading Scale



Statistical Method

- 235 subjects will be enrolled
- This will provide 85% power to detect a 20% difference in hair preservation, 15% in control group and 35% in scalp-cooling group
- Secondary endpoints include:
  - Wig/scarf use
  - Quality of life assessed by the EORTC QLQ-30, HADS and BIS.
- Study participants will be followed for 5 years post-study for time to first recurrence, overall survival, and site of first recurrence.