US Oncology Research Launches Innovative Clinical Trial Focused on Preventing Chemotherapy-Induced Hair Loss

Scalp cooling study underway to evaluate device that may prevent hair loss in oncology patients

The Woodlands, Texas (June 30, 2014) — Hair loss from chemotherapy can be one of the most distressing and troublesome side effects cancer patients face, often impacting their body image, sexuality and overall well-being. Patients who lose their hair also lose their privacy as a cancer patient, as hair loss is commonly associated with cancer treatment. Now, there may be a way to stop or greatly reduce the hair loss that can occur with certain chemotherapy treatments.

US Oncology Research—one of the largest community-based cancer research programs in the nation—and Baylor College of Medicine have recently launched a clinical trial to study a scalp cooling system designed to prevent chemotherapy-induced hair loss (alopecia). To date, 15 patients have been enrolled, and the study is now available at three US Oncology Research sites (listed below).

Cooling the scalp during chemotherapy causes the blood vessels in the scalp to constrict. Preliminary observation has shown this may reduce or prevent otherwise inevitable total hair loss caused by some chemotherapy regimens. By keeping the scalp at a constant cool temperature before, during and after infusion of chemotherapy drugs, damage to the cells in the hair root may be minimized. The US Oncology Research study, titled “Scalp Cooling Alopecia Prevention Trial (SCALP),” will examine the Orbis Paxman Hair Loss Prevention System. The goal is to determine the safety and effectiveness of the system in reducing alopecia in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy.

“Several preliminary studies have demonstrated the effectiveness of the Paxman Scalp Cooling System for some patients in preventing hair loss that often occurs as a result of chemotherapy,” said Cynthia Osborne, M.D., medical oncologist, Texas Oncology-Baylor Charles A. Sammons Cancer Center, and principal investigator for this study at US Oncology Research. “This clinical trial will provide the foundation for us to build credible evidence-based data, allowing us to make better decisions for our patients about whether this is a viable non-drug intervention for those who are concerned about hair loss during treatment.”

The Paxman Scalp Cooling System utilizes a soft lightweight silicone cap which is placed on the patient’s head. The “cold cap” is connected to a small compact refrigeration system which lowers the scalp temperature by circulating a special coolant through the cap. The cap maintains the scalp at a constant temperature throughout the treatment period. It is placed on the patient about a half-hour before the chemotherapy is administered and continues to be worn for approximately 90 minutes after the infusion is complete, depending on the type of drugs given.

“The cooling system is used extensively in several European countries, as well as Australia and Canada,” noted Julie Nangia, M.D., assistant professor, Lester & Sue Smith Breast Center, Baylor College of Medicine. “The observational results from these countries indicate that anywhere between 50 and 75 percent of patients keep their hair when the system is used. These are promising outcomes, as total hair loss is expected with these selected chemotherapy drugs.”

Approximately 50 participants are being recruited for the trial at three participating US Oncology Research sites: Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, Texas, led by Cynthia Osborne, M.D.; Texas Oncology-Memorial City, Houston, Texas, led by Frankie Ann Holmes, M.D., and Hematology-Oncology Associates of Northern New Jersey, P.A., Morristown, N.J., led by Steven Papish, M.D., F.A.C.P. Patients interested in participating in the study must meet the following criteria:
- Female, age 18 years or older
- 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.

“As a family business that came about after our chairman’s wife lost her hair while receiving chemotherapy, we know first-hand how devastating hair loss can be to cancer patients,” said Richard Paxman, managing director of Paxman Coolers, Ltd. “We are excited to have our system evaluated in this clinical trial, as it will add to the growing body of evidence demonstrating the effectiveness of our device, which has been used successfully by thousands of cancer patients around the world.”

Newly diagnosed breast cancer patients who are about to undergo chemotherapy are encouraged to contact one of the three participating US Oncology Research sites for more information.

**About US Oncology Research**
Supported by McKesson Specialty Health and The US Oncology Network, US Oncology Research draws from a network of experienced investigators and dedicated clinical staff who specialize in oncology clinical trials. US Oncology Research serves nearly 70 research sites and approximately 240 locations managing about 225 active trials at any given time. Physicians in the research network have enrolled more than 57,000 patients in nearly 1,300 trials since inception in 1992 and have played a role in 48 FDA-approved cancer therapies, nearly one-third of all cancer therapies approved by the FDA to date. For more information call (800) 482-6700 or visit [www.usoncology.com/oncologists](http://www.usoncology.com/oncologists).

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