Study Of Cold Cap Therapy For Prevention of Hairloss in Pediatric Patients Receiving Chemotherapy For Non-Malignant Indications and Solid Tumors

NCT04764357

Status	RECRUITING
Phase	Not Applicable
Sponsor	St. Jude Children's Research Hospital
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (4)

- Patients receiving a chemotherapeutic agent likely to cause alopecia. Any patient receiving the following drugs may experience complete alopecia (dose and schedule dependent). If they are receiving such a drug for a non- malignant indication or solid tumor, they may be suitable for inclusion in the study and may benefit from the use of a scalp cooling device. Of the commonly used intravenous single cytotoxic agents, those most likely to cause complete alopecia (dose and schedule dependent) include alkylating agents (cyclophosphamide, ifosfamide, busulfan, thiotepa), antitumor antibiotics (dactinomycin, doxorubicin, epirubicin, idarubicin), antimicrotubule agents (paclitaxel, docetaxel, ixabepilone, eribulin), and topoisomerase inhibitors (etoposide, irinotecan). Alopecia is less common or incomplete with bleomycin, low-dose epirubicin or doxorubicin (especially \<30 mg/m2), oral cyclophosphamide, fluorouracil, gemcitabine, melphalan, methotrexate, mitomycin, mitoxantrone, the platinums (oxaliplatin, cisplatin, and carboplatin), topotecan, and the vinca alkaloids. Antibody-drug conjugates are also associated with variable hair loss, which is agent specific.
- Diagnosed with a non-malignant condition (such as Sickle Cell Disease or Aplastic Anemia) OR Diagnosed with a solid tumor (non-brain tumor)
- Patients must be at least 7 years old
- Patients should have a head circumference of 50 cm or greater

Exclusion (7)

- Patients receiving a chemotherapeutic agent for a hematologic malignant/neoplastic condition.
- Patients with neoplasm of the brain or scalp, or present scalp metastasis, or high risk of metastatic disease to the brain or scalp (for example, neuroblastoma, melanoma or other skin malignancies, or patients who have had or are scheduled to undergo cranial irradiation.)
- Patients who are unfit for the study based on the opinion of the primary investigator and/or the patient's primary team.
- Patients with a previous history of adverse event associated with the Paxman scalp kit or scalp cooling device
- Patients with cold agglutinin disease or cold urticaria

... and 2 more (see full listing online)

Locations (1 total)

St. Jude Children's Research Hospital, Memphis, Tennessee, United States