RANDOMIZED PHASE III TRIAL OF NEOADJUVANT IMMUNOTHERAPY WITH RESPONSE-ADAPTED TREATMENT VERSUS STANDARD-OFCARE TREATMENT FOR RESECTABLE STAGE III/IV CUTANEOUS SQUAMOUS CELL CARCINOMA

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of invasive cutaneous squamous cell carcinoma (CSCC) or regional lymph node or in-transit metastasis of CSCC - previously untreated or recurrent CSCC - walking and able to do self-care, but unable to work; up and about at least 50% of waking hours - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- women who are pregnant or breastfeeding - history of solid organ or bone marrow transplant - no active, known, or suspected autoimmune disease for the past 5 years - current significant medical issues - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Procedure: Biospecimen Collection, Biological: Cemiplimab, Procedure: Computed Tomography, Radiation: Image Guided Radiation Therapy, Radiation: Intensity-Modulated Radiation Therapy, Procedure: Magnetic Resonance Imaging, Procedure: Positron Emission Tomography, Other: Questionnaire Administration, Procedure: Surgical Procedure, Procedure: Surgical Procedure
Conditions:
Cancer
Keywords:
Eyelid Squamous Cell Carcinoma, Recurrent Skin Squamous Cell Carcinoma, Clinics and Surgery Center (CSC)

More Information

Description: We are studying the use of immunotherapy before and after (in some cases) surgery to see if it will extend the length of time until the cancer returns compared to the usual approach. The usual approach for patients who are not in a study is treatment with surgery which may be followed by radiation. Participants will either get the study drug cemiplimab (REGN2810) before surgery for the cancer or will have up-front surgery. For those who receive cemiplimab (REGN2810), it will be given before surgery every 3 weeks for up to 12 weeks. In either case, participants may also receive radiation after surgery depending on the tumor tissue results from surgery.
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