

A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- inoperable, recurrent, or metastatic anal cancer - restricted from strenuous activity but can walk and are able to carry out work of a light or sedentary nature - requirements for lab results at a defined level (study staff will review) - history of significant heart disease

Exclusion Criteria:

- women who are pregnant or breastfeeding - previous use of systemic chemotherapy or other investigational drugs - prior immunotherapy - active autoimmune disease or history of autoimmune disease - other primary cancer within the last 3 years - intermittent peripheral neuropathy - additional exclusion criteria that study staff will review

Conditions & Interventions

Interventions:

Drug: Carboplatin, Biological: Nivolumab, Drug: Paclitaxel

Conditions:

Cancer

Keywords:

Anal Cancer

More Information

Description: We are looking at the addition of nivolumab to chemotherapy compared to usual treatment (chemotherapy alone) for the treatment of anal cancer that has spread to other places in the body. Immunotherapy, such as nivolumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Chemotherapy drugs, such as carboplatin and paclitaxel, work in different ways to stop the growth of tumor cells. Giving nivolumab with chemotherapy may help doctors find out if the treatment is better or the same as the usual approach.

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Phase: PHASE3

IRB Number: MMCORC037

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