

A Phase Ib open label randomised clinical trial to evaluate safety and efficacy of BI 770371 in combination with pembrolizumab with or without cetuximab compared with pembrolizumab monotherapy for the first-line treatment of patients with metastatic or recurrent Head and Neck Squamous Cell Carcinoma (HNSCC)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed metastatic or recurrent Head and Neck Squamous Cell Carcinoma (HNSCC) of the primary tumor location of oral cavity, oropharynx, hypopharynx, and larynx - have not received prior systemic treatment for metastatic or recurrent HNSCC - do not have contraindications to pembrolizumab - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- Nasopharyngeal cancer (NPC) - progressive HNSCC within 6 months of completion of systemic therapy - prior allogeneic stem cell or solid organ transplantation - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:

Cancer

Keywords:

Clinics and Surgery Center (CSC), Head and Neck Squamous Cell Carcinoma, HNSCC

More Information

Description: The goal of this study is to find out whether combining different study drugs makes tumors shrink in people with advanced head and neck cancer. This type of cancer is in the mouth, nose, throat, and sinuses. The study drugs are antibodies that act in different ways against cancer. BI 770371 and pembrolizumab may help the immune system fight cancer. Cetuximab blocks growth signals and may prevent the tumor from growing. Participants are put into 1 out of 3 groups, by chance (like drawing names from a hat), and which of the study treatments participants will receive.

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Phase: PHASE1

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