Inhaled Budesonide for REcurrence Prevention and Adjuvant THerapy in Checkpoint Inhibitor Pneumonitis

NCT06860542

Status	RECRUITING
Phase	Phase 2
Sponsor	AHS Cancer Control Alberta
Enrollment	94 participants

Key Eligibility Criteria

Inclusion (8)

- Patients must be 18 years of age, or older on the day of signing informed consent and be willing and able to provide written informed consent/assent and, in the opinion of the Investigator, comply with protocol tests and procedures
- Patients require histologically confirmed solid tumour undergoing immune checkpoint inhibitor (ICI) therapy
- Diagnosis of first documented diagnosis of Checkpoint Inhibitor Pneumonitis (CIP) made per European Society for Medical Oncology (ESMO)/American Society for Medical Oncology (ASCO) guidelines with severity \>/grade 2 by Common Terminology Criteria for Adverse Events (CTCAE)v5.0
- a. Per ASCO/ESMO consensus guidelines, workup must include a compatible clinical picture, plus/minus supporting radiographic evidence (chest x-ray or preferably computed tomography (CT)), combined with clinical and/or microbiologic ruling out of alternative etiologies including infections or pulmonary disease progression. This includes a negative COVID test. Bronchoscopic sampling is not required, but can be considered.
- Be able to effectively operate and use budesonide delivery method (Turbuhaler®), either independently or with aid of caregiver who anticipates being able to do so throughout trial period

... and 3 more (see full listing online)

Exclusion (10)

- Diagnosis of interstitial lung disease (ILD) active (clinically and radiologically evident) within last year prior to diagnosis of CIP
- Current (within last two weeks), active (not medically able or unwilling to discontinue prior to treatment start) and regular (2 or more times per week) use of inhaled steroids (for any indication) or systemic (\>10mg prednisone equivalent) corticosteroids (for indication other than CIP) at time of randomization
- Receiving systemic, non-chemotherapy immunosuppressive agent at time of randomization (hydroxychloroquine is acceptable)
- Use of a medication with significant interaction with inhaled budesonide (HIV protease inhibitors, ketoconazole or other potent CYP3A4 inhibitors), unless deemed required and safe by co-investigator.
- Known poorly controlled diabetes, defined as A1c \>10, prior to initiation of steroids for CIP

... and 5 more (see full listing online)

Locations (1 total)

Arthur J.E. Child Comprehensive Cancer Centre, Calgary, Alberta, Canada