

Summary: A 26-week treatment, multicenter, randomized, double-blind, double-dummy, parallel-group study to assess the safety of two doses of investigational drug in patients with moderate to severe persistent asthma using salmeterol as an active control.

Inclusion Criteria:

- Male or female patients aged ≥ 12 years
- Patients with a diagnosis of moderate to severe asthma
- Patients who have used treatment with a bronchodilator either daily or on-demand for at least 1 month.

Exclusion Criteria:

- Patients who have used tobacco products within 12 months prior or who have a 10pack year smoking history.
- Pregnant or nursing (lactating) women
- Patients who suffer from COPD
- Patients who do not maintain regular day/night, waking/sleeping cycles (e.g., night shift workers)
- Patients who have had treatment with investigational drugs at the time of enrollment, or within the last 30 days
- Patients with pulmonary disease, pulmonary tuberculosis (unless confirmed by chest x-ray to be no longer active) or clinically significant bronchiectasis
- Patients who have had a respiratory infection in the past 6 weeks.
- Patients with Type I diabetes or uncontrolled Type II diabetes (including patients with a history of blood glucose levels consistently outside the normal range or HbA_{1C} >8.0%)
- Any patient with lung cancer or a history of lung cancer.
- Any patient with active cancer or a history of cancer with less than 5 years disease free survival time

Contact:

Amy Christian, RN, Clinical Research Coordinator

Telephone: 785-368-0745

Email: achristian@stormontvail.org