Protocol CAUSE-03 / CHEETAH

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years to 17 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or parent guardian must be able to understand and provide informed consent and assent
2. Have a primary place of residence in one of the pre-selected recruitment census tracts as outlined in the Protocol CAUSE-03 Manual of Operations (MOP)

a. Participants who do not live in the pre-selected census tracts but live within the Office of Management and Budget (OMB) defined Metropolitan Statistical Area and have publicly funded health insurance will qualify for inclusion
3. Either:

1. Have had a diagnosis of asthma made > 1 year prior to recruitment; participants who received an asthma diagnosis by a clinician <= 1 year prior to recruitment must report that their respiratory symptoms were present for more than 1 year prior to recruitment (asthma group), or
2. No report of ever being diagnosed with asthma (non-asthma group)

    1. Either:
3. Require at least Step 2 therapy at the Screening/Enrollment Visit (asthma group), or

4. Have not used any asthma medications in the prior year (non-asthma group)

    1. Are able to perform acceptable and repeatable spirometry per American Thoracic Society (ATS) criteria prior to enrollment
    2. Have documentation of current medical insurance with prescription coverage at the Screening/Enrollment Visit
    3. Participant and/or parent guardian has a smartphone compatible with the study electronic Patient Reported Outcomes (ePRO) system, Medidata Patient Cloud, and is willing to download one application for study use

Exclusion Criteria:

1. Parent or guardian is not able or willing to give written informed consent or comply with study protocol
2. Have concurrent medical problems that would require systemic corticosteroids or other immunomodulators during the study
3. Are currently receiving immunotherapy
4. Are currently receiving treatment with a biologic therapy or have received a biologic therapy within 3 months prior to enrollment
5. Are currently requiring greater than fluticasone 500 mcg bid plus Long-Acting Beta Agonists (LABA) one puff twice daily or its equivalent plus Long Acting Muscarinic Antagonists (LAMA) and/or individuals using oral corticosteroids daily or every other day for more than 14 days at the time of the Screening/Enrollment Visit
6. Are currently pregnant or lactating, or plan to become pregnant during the time of study participation. Females of child-bearing potential (post-menarche) must be abstinent or use a medically acceptable birth control method throughout the study (i.e., oral subcutaneous, mechanical, or surgical contraception)
7. Have a known, pre-existing clinically important lung condition other than asthma.
8. Have a current malignancy or previous history of cancer in remission for less than 12 months prior to enrollment
9. Have a known immunodeficiency disease
10. Use of investigational drugs within 4 weeks of enrollment
11. Have past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the site investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements or that may impact the quality or interpretation of the data obtained from the study
12. If in the asthma group, will not allow the study clinician, an asthma specialist, to manage their disease for the duration of the study or who are not willing to change their asthma medications to follow Protocol CAUSE-03 CHEETAH
13. If in the non-asthma group, having bronchodilator reversibility (improvement in Forced expiratory volume in 1 second (FEV1) with albuterol > = 10%) at the Screening/Enrollment visit
14. Have had a life-threatening asthma exacerbation in the last 2 years requiring intubation, mechanical ventilation or resulting in a hypoxic seizure. Potential participants may be reassessed as outlined in the Protocol CAUSE-03 Manual of Procedures (MOP)

Conditions & Interventions

Conditions:
Asthma
Keywords:
Asthma, Observational study, Children

More Information

Description:
This is a one-year longitudinal, observational study of 250 urban children and adolescents with asthma and 60 without asthma, ages 6-17 years old.

Participants with asthma will require daily controller therapy with inhaled corticosteroids ICS (at least Step 2 therapy). Those without asthma cannot have used asthma medications in the year prior to enrollment and cannot demonstrate bronchodilator reversibility at baseline. Phenotypic characteristics will be established at baseline, and the participants will be seen at scheduled visits over 12 months. Each participant will be asked to monitor and self-report cold symptoms and will be asked to complete up to three cold visits

Contact(s): Molly Brausch-Bradner - Molly.Brausch-bradner@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase:
IRB Number:
System ID: NCT06136091
