Clinical Trial Document

Official Title:

A Randomized, Double-Blind, Placebo-Controlled Clinical Trial Comparing the Efficacy of an Antibiotic or an Inhaled Corticosteroid With Placebo in Children With Prolonged Cough

ClinicalTrials.gov Identifier (NCT Number):

NCT: To be assigned

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ClinicalTrials.gov Registration – English Text with Statistical Analysis Plan

Brief Title

Randomized, Double-Blind Trial of Antibiotic or Inhaled Corticosteroid Versus Placebo in Children With Prolonged Cough

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A Randomized, Double-Blind, Placebo-Controlled Clinical Trial Comparing the Efficacy of an Antibiotic or an Inhaled Corticosteroid With Placebo in Children With Prolonged Cough

Brief Summary

Prolonged cough lasting more than four weeks is common in young children but often remains unexplained after standard clinical evaluation. Despite this, inhaled corticosteroids and antibiotics are frequently prescribed, although evidence for their effectiveness in children without a clear underlying diagnosis is limited. This study evaluates whether inhaled fluticasone is more effective than placebo in children with prolonged dry cough, and whether oral amoxicillin–clavulanic acid is more effective than placebo in children with prolonged wet cough.

Detailed Description

Children aged 1–6 years with prolonged cough (>4 weeks) and no identifiable underlying disease after standardized evaluation are enrolled. All participants undergo structured diagnostic investigations according to ERS 2020 guidelines before treatment initiation. Children with dry cough receive inhaled fluticasone or placebo for eight weeks, and children with wet cough receive amoxicillin–clavulanic acid or placebo for fourteen days in a parallel-group, double-blind design.

Study Design

Interventional, Phase 3, randomized, double-blind, parallel-group, placebo-controlled clinical trial.

Statistical Analysis Plan

Analysis Populations

The primary analysis population is the intention-to-treat (ITT) population, including all randomized participants according to their assigned treatment group, regardless of treatment adherence. A per-protocol (PP) population will be used for sensitivity analyses,

excluding participants with major protocol deviations, early discontinuation of treatment (within 3 days), or treatment adherence below 50%.

Primary Endpoint Analysis

The primary endpoint is the proportion of participants achieving significant cough improvement during the treatment period. Significant improvement is defined as complete resolution of cough or at least a 75% reduction in cough symptom score compared with baseline for three consecutive days. Baseline is defined as the mean VCD score from the 14-day pre-treatment cough diary.

Comparisons between active treatment and placebo within each cough phenotype group will be performed using Fisher's exact test, with results presented as proportions and 95% confidence intervals.

Secondary Endpoint Analyses

Secondary endpoints include time to cough improvement, changes in cough frequency (VCD) and severity (VAS), safety outcomes, and diagnostic findings. Time-to-event outcomes will be analysed using Cox proportional hazards regression.

Missing Data

Missing data may be handled using simple imputation methods where appropriate. Longitudinal symptom diary data may be imputed using last observation carried forward.

Statistical Significance

All analyses will be two-sided with a significance level of 0.05 and performed using SPSS software.