

## **TITLE**

Evaluation of long-acting bronchodilator therapy in children with asthma: a prospective observational study.

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**Duration:** 2016-2020

## **SUMMARY OF PROJECT**

**Objectives:** 1) To assess the risk of severe asthma exacerbations in children with asthma treated with long acting bronchodilators (LABAs), compared with those treated only with inhaled corticosteroids (ICs); 2) To assess the health related quality of life of children with asthma in Spain and its relationship with treatment adherence and symptom control, according to the type of treatment and age.

**Methods:** A prospective multicentre observational study, with 16 months of follow-up, on children with persistent asthma in Spain (n = 261). Inclusion criteria: 6-14 years old, asthma diagnosis, and treatment during  $\geq 6$  months of the previous year with LABAs or ICs without LABAs. Exclusion criteria: previous history of therapy with Omalizumab, or concomitant respiratory disease. Follow-up includes computer assisted telephone interviews (every 6 months), and monthly questionnaires administered through the ARCA app (Asthma Research in Children and Adolescents).

**Results:** No differences were found in the risk of serious adverse events in children, neither in the cohort results nor in the systematic reviews on Salmeterol and Formoterol safety. The EuroQol-Youth (EQ-5D-Y) demonstrated good acceptability, validity and reliability when administered through the App, and it will allow evaluating the impact of asthma on the healthrelated quality of life of the children and adolescents in the ARCA cohort.

**Conclusions:** The potential risks of LABAs must be weighed against the benefits experienced by the children and adolescents under a combined therapy.