

# Assessment of treatment with Long Acting Bronchodilators in children with asthma: an observational prospective study.

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## SUMMARY

### 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 multicenter 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 health-related 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.