QUALITY OF LIFE OF PEDIATRIC PATIENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER AND OPPOSITIVE DEFIANT DISORDER: AN ITALIAN DOUBLE-BLIND PLACEBO-CONTROLLED STUDY WITH ATOMOXETINE

P. Curatolo[1], F. Mancini[2], G. Dell'Agnello[2], R. Pino[2] and the LYCY Study Group

[1]Neuropsichiatria Infantile – Policlinico di Torvergata - Clinica Sant'Alessandro – Roma
[2]Eli Lilly Italia

Objective: The aim of this study is to evaluate the effectiveness of atomoxetine in improving the quality of life of pediatric patients with ADHD and ODD, non-responders to a previous psychological intervention with parent support.
Methods: This is a multicentre, randomised, placebo-controlled, trial conducted in patients aged 6 to 15 years, with ADHD and ODD diagnosed according to the DSM-IV criteria. To be elegible in the study, patients had a score at least 1.5 SD above the age norm for the ADHD subscale of the Swanson, Nolan and Pelham Rating Scale-Revised (SNAP-IV) and a SNAP-IV ODD subscale score of at least 15. For the first 6 weeks of the trial the investigators provided a standardized parent training to the tutors of all patients. At the end of this period only those subjects considered non-responders to parent support were randomized to take atomoxetine (up to 1.2 mg/kg/day) or placebo for the following 8-week period of double-blind treatment. The effect on emotional and social well being of the child and the family was assessed comparing atomoxetine and placebo in changing the total score of the Child Health and Illness Profile – Child Edition at the end of the double-blind phase.
Results and conclusion: The results of the trial are not available yet but they will be presented during the symposium. This study, with 154 patients of both sexes recruited from 13 sites, is the first trial conducted in Italy to investigate the effect of atomoxetine on quality of life in a large population of ADHD patients.