149.00

Novalac AR, a NEW ANTIREGURGITATION MILK FORMULA FOR THE TREATMENT OF MILD TO MODERATE GASTROESOPHAGEAL REFLUX IN INFANTS

I. Xinias, K. Spiroglou, V. Demertzidou, E. Karatza, C. Panteliadis
Third Pediatric Department, Aristotle University, Thessaloniki, Greece
xinias@med.auth.gr

Background: antiregurgitation milk formulas (AMF) increase the duration of gastroesophageal reflux (GOR) episodes and have been associated with diarrhea, constipation and cough in infants. The aims were to determine the efficacy of a new AMF, Novalac AR, in the clinical and laboratory setting in infants with proved GOR, and to investigate any possible adverse events. Methods: infants with GOR who were not responsive to standard treatment were eligible for the study. Infants in the treatment group were managed for 4 weeks with a specific AMF, Novalac AR, with specially selected cornstarch and increased amount of caseine) and those in the control group were given a standard milk-formula. Furthermore vomiting, regurgitation, bowel movements, cough-events were noted before and during study. A 2nd pHmonitoring was performed after 4 weeks in both groups. Results: sixty-eight infants (mean [SD] age 3.3 [1.4] months) were included in the study: 36.8% had mild GOR; 48.5% moderate GOR; 14.7% severe GOR. Significantly more infants in treatment group (51.7%) than in control group (17.2%) with mild or moderate GOR, had normal second pHmonitoring ($p<0.05$). Changes in the reflux index and the mean number of vomiting and regurgitation episodes were significantly different between the two groups ($p<0.05$). No significant difference in changes in the mean number of bowel movements and cough-events was found between the 2 groups. Conclusions: Infants with mild or moderate GOR can be managed effectively with Novalac AR. Improved clinical and laboratory findings were seen in the majority of infants, without adverse events.