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BELGISCHE VERENIGING
VOOR KINDERGENEESKUNDE
SOCIÉTÉ BELGE DE PÉDIATRIE

Vol. 1

Proceedings 2010

Belgische Vereniging voor kindergeneeskunde - Société Belge de Pédiatrie

Posters Nutrition



A pilot trial on acceptability, tolerance, and efficacy of a thickened extensive casein hydrolysate (Allernova AR®)

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Rationale

Regurgitation, irritability, and vomiting are common in infants with mild gastro-esophageal reflux disease (GERD) but are indistinguishable from regurgitation, irritability and vomiting caused by food allergy. Both conditions occur in about 5 % of infants. Thickened formula has been shown effective in the treatment of (troublesome) regurgitation and mild GERD, and an extensive hydrolysate is recommended in the treatment of cow milk allergy (CMA).

Methods

A prospective, open trial was conducted to evaluate the efficacy of an extensive casein-hydrolysate thickened with specifically treated starch in 24 infants with a suspected diagnosis of mild GERD and/or gastro-intestinal manifestations of CMA (all infants regurgitated or vomited > 4 times/day). Previous interventions (at least one dietary change and one drug for GERD) had failed in all infants.

Results

6/24 infants (25 %) dropped out because of pyloric stenosis (n:1), urinary tract infection (n:1), severe combined immune deficiency (n:1), no improvement of symptoms (crying and vomiting) (n:3). The formula was well tolerated and accepted in 18/24 infants, and administered up to the age of 6 months. In total, "Allernova-AR®" was consumed during 2165 trial-days. Objective arguments for CMPA were observed in 8/18 infants (eosinophilia (n:3), allergic colitis (n:2), partial atrophy villi (n:2); positive skin prick test (n:2)). The mean duration of feeding was 125 days. Weight and length evolution were within normal range. According to the diaries kept by the parents, the incidence of regurgitation at baseline (mean 5.85) decreased after one week by more than 50 % (mean 2.12)(p:<0.001). The Infant-GER-Questionnaire showed a clinical meaningful improvement of at least 5 points in all 18 infants tolerating the new formula.

Conclusion

The results of this pilot trial suggest that a commercially thickened extensive casein-hydrolysate is an effective approach in infants presenting with symptoms suggestive for CMA and mild GERD. Given the frequent simultaneous occurrence in infants of symptoms suggesting CMPA and/or GERD, Allernova-AR® provides practitioners an effective and safe therapeutic option, improving the quality of life of the infants and reassuring parents, treating CMPA and reflux.

