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# The clinical effect of a new infant formula in term infants with constipation: a double-blind, randomized cross-over trial

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## Abstract

### Background

Nutrilon Omneo (new formula; NF) contains high concentration of *sn*-2 palmitic acid, a mixture of prebiotic oligosaccharides and partially hydrolyzed whey protein. It is hypothesized that NF positively affects stool characteristics in constipated infants.

### Methods

Thirty-eight constipated infants, aged 3–20 weeks, were included and randomized to NF ( $n = 20$ ) or a standard formula (SF;  $n = 18$ ) in period 1 and crossed-over after 3 weeks to treatment period 2. Constipation was defined by at least one of the following symptoms: 1) defecation frequency  $< 3$ /week; 2) painful defecation; 3) abdominal or rectal palpable mass.

### Results

Period 1 was completed by 35 infants. A significant increase in defecation frequency (NF: 3.5 pre versus 5.6/week post treatment; SF 3.6 pre versus 4.9/week post treatment) was found in both groups, but was not significantly different between the two formulas ( $p = 0.36$ ). Improvement of hard stool consistency to soft stool consistency was found more often with NF than SF, but did not reach statistical significance (90% versus 50%; RR, 1.8; 95% CI, 0.9–3.5;  $p = 0.14$ ). No difference was found in painful defecation or the presence of an abdominal or rectal mass between the two groups. Twenty-four infants completed period 2. Only stool consistency was significantly different between the two formulas (17% had soft stools on NF and hard stools on SF; no infants had soft stools on SF and hard stools on NF, McNemar test  $p = 0.046$ ).

### Conclusion

The addition of a high concentration *sn*-2 palmitic acid, prebiotic oligosaccharides and partially hydrolyzed whey protein resulted in a strong tendency of softer stools in constipated infants, but not in a difference in defecation frequency. Formula transition to NF may be considered as treatment in constipated infants with hard stools.

