



## International Scientific Association for Probiotics and Prebiotics

*An international non-profit association of scientists dedicated to advancing the  
fundamental and applied science of probiotics and prebiotics*

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### ISAPP Responds to Utrecht Warning about Probiotics

The report from the University of Utrecht in the Netherlands ([www.physorg.com/news120312362.html](http://www.physorg.com/news120312362.html)) warning about probiotic use for patients with pancreatitis is important, but has to be taken in context.

The study used Ecologic<sup>®</sup> 641 consisting of 6 strains of viable and freeze-dried bacteria from the species *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus salivarius*, *Lactococcus lactis*, *Bifidobacterium bifidum* and *Bifidobacterium lactis* in a total daily dose of  $10^{10}$  live bacteria administered through a nasal tube directly into the intestine, providing a dose to the intestine higher than would be delivered in most probiotic foods. The rationale and design of this study have been published ([www.pubmedcentral.nih.gov/articlerender.fcgi?artid=526218](http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=526218)). In short, the study was designed to determine if this product could reduce the number of infectious complications during hospital stays for patients with a rare but serious illness. This is unlike almost all other uses of probiotics which constitute foods or supplements intended to maintain or enhance health.

Based upon the information provided in the press release and media reports, post-mortems had ruled out any possibility that the probiotics caused infection, and thus it is not apparent that probiotics played any role in mortality. The scientific community awaits full details of the study to be published in order to fully assess this situation. Information such as cause of mortality and if placebo and treatment groups were comparable with respect to severity of disease, medications and other parameters will be very important in interpreting this outcome, and to determine if patient death was an unfortunate result from their medical condition, not the use of probiotics.



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It is difficult to foresee a way in which robust probiotic products could cause such harm. The strains in the probiotic product used in this study were of species that have been broadly and safely used in foods and supplements worldwide, have been used in clinical trials with no significant reported adverse incidents attributed to them, are present on the European Union Qualified Presumption of Safety list and in many cases have been affirmed as GRAS in the United States. In other words, these species have a convincing safety record for use in foods and supplements. Of note, the product Ecologic<sup>®</sup> 641 has only been used in clinical settings and is not available on the market.

ISAPP, along with scientists researching probiotics and companies producing clinically documented products, take safety issues very seriously. Adverse events in any clinical study are regrettable. However, consumers and healthcare professionals should recognize that this report should not be generalized to all probiotics for all uses.

ISAPP ([www.isapp.net](http://www.isapp.net)) is a scientific organization whose mission is to disseminate accurate information on probiotics and prebiotics. **In the opinion of the ISAPP Board of Directors, this report using Ecologic<sup>®</sup> 641 in patients with acute pancreatitis does not call into question the safety of probiotics** comprised of *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus salivarius*, *Lactococcus lactis*, *Bifidobacterium bifidum* and *Bifidobacterium lactis* for the **generally healthy population to consume as foods and supplements.**

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