Letter: An observational trial: Patient profile of users of Secomet V®

To the editor: Subsequent to a report published by Natasha Bolognesi in Nature Medicine in 2006[1] on a "herbal" product called Secomet V® researchers of the University of Pretoria undertook an observational trial to document the demographics, quality of life and disease profile of patients who purchase Secomet V®, a product that contains selenium, L-glutamin and high levels of a carbohydrate derived fulvic acid (CHD-FA). No traces of any plant extracts could be found in the product.

Two hundred users of Secomet V® completed the questionnaire. During this study it became obvious that the majority of users were HIV positive. This study was followed up by a second observational trial to determine the effects of this product on health-related outcomes in patients taking the product. Volunteers who participated in the first trial contacted the research centre on a voluntary basis. Both these trials were approved by the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria, South Africa and were overseen by an independent principal investigator (clinical trial specialist).

Sixty-six patients completed the second trial. Of these, 46 patients were voluntarily users of Secomet V® whereas the other 20 patients were not using this product. All the patients on the second trial were HIV positive, more than 18 years of age, and signed a written informed consent form. As it was an observational trial, compliance could not be enforced. Visits were required upon enrolment as well as on day 90. Blood samples were taken during both visits to determine CD4 counts and viral loads as well as electrolyte balance, AST, ALT and S-lactate dehydrogenase levels. The RAND SF-36 item questionnaire and the Karnofsky performance status (KPS)-scale were used to assess quality of life and patients' physical functional levels. No adverse events occurred during the study.

It was found that Secomet V® caused no liver or renal toxicity in the patients. A statistically significant reduction of the viral loads (Table I) and improvement in the health survey was documented in the Secomet V® group, but not the control group. It can therefore be concluded that Secomet V® is well tolerated in patients suffering from HIV and can lead to an improvement in their well being which supports further investigation to test the validity of Secomet V® as a possible complementary product to boost the well being of HIV positive patients.

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Reference

1. Bolognesi N. Bad Medicine. Nature Med 2006;12:723–724.

Table I: Effect of The Product *vs* The Control on the viral load

	HIV-1 RNA copies (cp/ml)			
	Before		After	
	Mean	± SD	Mean	± SD
Secomet V®	146 844	271 022	*72 767	127 567
Control	15 208	33 760	336 898	142 4041

* Significantly different from baseline/before ($p < 0.05$)