

Clinical research applied to nutraceuticals

A.F.G. Cicero, Medical and Surgical Sciences Dept, University of Bologna

A large body of preclinical evidence suggest that a number of nutraceuticals is able to modulate physiological pathways and potentially to improve human health. The main difficulty to test nutraceuticals in humans is the need to not search for a specific efficacy but simply an effect on human health, because (at least theoretically) nutraceuticals have not to be endorsed for therapeutic properties. Anyway, if the effect of a nutraceutical has to be studied in a clinical trial, the researcher have to follow all the rules foreseen by the so-called Good Clinical Practice. In particular, the study has to be well-designed, having an adequate sample size, an adequate length of the follow-up, a correct double-blind randomization procedure, a detailed definition of the Standard Operator Procedures, and a prespecified statistical analysis (Sirtori et al., 2015). Moreover the outcome measurement has to be highly standardized and with a practical applicability. Considering the scarce possibility that a long-term trial on hard outcomes is carried out on nutraceuticals, some intermediated/surrogate outcomes could be considered, being them laboratory or instrumental parameters. For instance, if we need to test the potential cardiovascular preventive efficacy of a nutraceutical, we could concentrate on metabolic or inflammatory parameters, or on instrumental validated tests such as flow-mediated dilation or pulse wave velocity (Cicero et al., 2014). Example of well-designed double-blind, randomized clinical trials evaluating the long-term effects on nutraceuticals on specific hard health outcomes (morbidity and mortality) exist. The most interesting ones are the Q-SYMBIO trial on Coenzyme Q10, the JELIS trial on omega-3 polyunsaturated fatty acids, and the on-going COSMOS trial on cocoa polyphenols (Borghi & Cicero, 2017).

Borghi & Cicero AF (2017). *Br J Clin Pharmacol*. 83, 163-171.

Sirtori et al. (2015). *Ann Med*. 47, 447-56.

Cicero et al. (2014). *Curr Vasc Pharmacol*. 12, 565-71.