

Letter to the editor

Up a blind alley without double-blind controlled trials

In the comments of Longo et al. (1) concerning our recent article on specific oral tolerance induction (SOTI) in this Journal (2), the authors criticize the requirement for double-blind, placebo-controlled clinical trials of the efficacy and safety of SOTI and its influence on the long-term outcome of food allergy. However, especially in the case of cow's milk (CM) and hen's egg (HE), most children become spontaneously tolerant over time. Therefore, prospective and double-blind, placebo-controlled trials are needed to distinguish between the natural course of food allergy and the effects of SOTI (3). This is especially true for CM and HE allergy. In cases such as

peanut allergy, where there is a greater likelihood of severe clinical symptoms and a much less favourable long-term outcome, it is important to proceed very carefully, and controlled, open trials may be appropriate.

The psychological influences on clinical reactions are manifold and overt in allergic diseases. The argument that blinding of SOTI is not possible due to subjective symptoms in the verum group is not confirmed by our experience. Subjective symptoms are often observed in the placebo group in double-blind, placebo-controlled oral food challenges (DBFCFC) – the gold standard in food allergy diagnostics.

In general, and in the case of SOTI, it would be unscientific to perform studies without the reliable control provided by a double-blind procedure. In contrast to the conclusion of Longo et al. (1), is precisely the rejection of double-blind, controlled trials, which would in fact 'contribute to leaving SOTI in a grey area of poorly standardized practice'.

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References

1. Longo G, Berti I, Barbi E. To throw the baby out with the bathwater: double blinding for specific oral tolerance induction. *Allergy* 2006;**61**.
2. Niggemann B, Staden U, Rolinck-Werninghaus C, Beyer K. Specific oral tolerance induction in food allergy. *Allergy* 2006;**61**:808–811.
3. Rolinck-Werninghaus C, Staden U, Mehl A, Hamelmann E, Beyer K, Niggemann B. Specific oral tolerance induction with food in children: transient or persistent effect on food allergy? *Allergy* 2005;**60**:1320–1322.