

## **Reviewer's report**

**Title:** Randomised controlled trial of food elimination diet based on IgG antibodies for the prevention of migraine

**Version:** 1 **Date:** 5 June 2011

**Reviewer:** MUSTAFA Dr. ERTAS

### **Reviewer's report:**

Participant's recruitment is poor, as no clinical diagnosis of migraine has been performed by specialist, but only by the subjective interpretation of the patient. The authors also highlight this.

Moreover, in the introduction the authors have cited a paper and criticized that "this study was tightly controlled and is probably not representative of the majority of patients who seek ELISA testing because of their headache". That is not a weakness of that study but the strength of that study compared to the present paper.

For me the question arises if the authors are addressing headache or migraine patients, which are 2 different entities. Therefore the name "migraine" should not appear in the title.

Furthermore the citation is incorrect, it must be 27.

Several factors can contribute to the low success rate of the study. One might be addressed to the test system itself.

- What is the setup of the test system? Did they test 113 single food antigens or have they performed pooled test as well. If yes, reliability of the results is questionable.

- Blood sampling procedure: Samples were not collected by a health care specialist, but by the patient himself. At this point you have no positive identification of the participant.

- Pin prick test blood sampling is not appropriate and yields in low reproducibility. Can the author provide reproducibility data for the test system?

- Another weakness of the trial is the relative small number of tested food. In elimination diets it is essential to eliminate all relevant food. This makes traditional elimination diets so laborious and difficult for the patient. Therefore a test system aiming to identify hazardous food must cover more than 95 % of commonly consumed food. Also the "true diet" should not contain any not tested food. I doubt that this has been achieved.

In dietary intervention studies, compliance is a most important factor. 83% of the diet group returned their questionnaire and 52% from them returned their diet diaries. Compliance in the intervention group is unacceptable.

No professional follow-up, guidance or assistance of the patient was offered. This

might also explain why in the first 4 weeks a relative improvement has been seen (patients are still motivated) and with ongoing time compliance became lesser.

This paper has strong deficiencies in respect to the study design, recruitment, compliance, and no medical control and assessment of the subjects, not meeting the criteria for a scientific paper.

Due to the huge amount of uncertainties, also acknowledged by the authors, this paper has no new information to offer and is of limited interest.

**Level of interest:** Reject as not of sufficient priority to merit publishing in this journal

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests' below