

Determination of the symptoms of aspartame in subjects who have previously reported symptoms compared to controls: a pilot double blind placebo crossover study

Area of research interest: [Chemical hazards in food and feed](#)

Study duration: 2009-07-01

Project code: FS231010 (T01054)

Conducted by: University of Hull

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Background

A number of individuals reported adverse reactions after consuming food and drink containing aspartame. Whilst numerous research studies and risk assessments have shown aspartame can be consumed safely, individual reports of these reactions persist. Given this continuing anecdotal evidence, European regulatory authorities, including the our organisation, feel it's appropriate to see if more can be found out about these alleged effects. This pilot study aimed to determine the feasibility and power required for an effective full scale study to address the concerns of the public.

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Research Approach

This double blind placebo controlled pilot study aimed to record any effects from eating a snack bar that may or may not contain aspartame, in a safe controlled clinical environment. The study recruited fifty individuals who report reactions, including (but not exclusively) headaches and nausea, after consuming aspartame and fifty individuals who normally consume foods containing aspartame without problems acted as controls.

Subjects were asked to complete general health and wellbeing questionnaires, they also provided blood and urine samples. The samples were analysed to determine the effect of aspartame consumption on plasma and urinary metabolite profile. The data was assessed to determine the suitability of the product and the methodology in order to determine the feasibility and power required for an effective full scale study.

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Results

The study concluded that the participants who were self-diagnosed as sensitive to aspartame showed no difference in their response after consuming a cereal bar, whether it contained aspartame or not. The study looked at various factors including psychological testing, clinical observations, clinical biochemistry and also metabolomics (which is the scientific study of small molecules generated by the process of metabolism).

The Hull/York paper was peer reviewed by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in December 2013. COT concluded that 'the results presented did not indicate any need for action to protect the health of the public.