Abstract

A combined single-blind, double-blind, placebo-controlled study to determine the reproducibility of hypersensitivity reactions to aspartame.

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Abstract

Aspartame is an O-methyl ester composed of phenylalanine and aspartic acid. After its final approval as a sweetener in 1981, a number of reports of adverse reactions to aspartame appeared in the literature. To explore the pathogenesis of such reactions, we initiated a study in July 1986 to identify subjects with hypersensitivity reactions to aspartame with blinded challenge procedures. The study was closed after 32 months. During that time, we advertised in local newspapers and worked closely with the local community of allergists and dermatologists in an attempt to recruit subjects with hypersensitivity reactions to aspartame. A total of 61 self-referrals and physician referrals were screened, with 20 referrals evaluated in clinic. After this evaluation, 12 patients underwent single- and double-blind challenge with up to 2000 mg of aspartame. No subject with a clearly reproducible adverse reaction to aspartame was identified. In summary, we found that it is difficult to recruit study subjects with a history of hypersensitivity reactions to aspartame and that subjects who believed themselves allergic to aspartame did not have reproducible reactions.

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