

Synthetic food coloring and behavior: A dose response effect in a double-blind, placebo-controlled, repeated-measures study

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Abstract

Objective: To establish whether there is an association between the ingestion of synthetic food colorings and behavioral change in children referred for assessment of "hyperactivity."

Participants: From approximately 800 children referred to the Royal Children's Hospital (Melbourne) for assessment of suspected hyperactivity, 200 were included in a 6-week open trial of a diet free of synthetic food coloring. The parents of 150 children reported behavioral improvement with the diet, and deterioration on the introduction of foods noted to contain synthetic coloring. A 30-item behavioral rating inventory was devised from an examination of the clinical histories of 50 suspected reactors. Thirty-four other children (23 suspected reactors, 11 uncertain reactors) and 20 control subjects, aged 2 to 14 years, were studied. **Design:** A 21-day, double-blind, placebo-controlled, repeated-measures study used each child as his or her own control. Placebo, or one of six dose levels of tartrazine (1, 2, 5, 10, 20, 50 mg), was administered randomly each morning, and behavioral ratings were recorded by parents at the end of each 24 hours. **Results:** The study identified 24 children as clear reactors (19 of 23 "suspected reactors," 3 of 11 "uncertain reactors," and 2 of 20 "control subjects"). They were irritable and restless and had sleep disturbance. Significant reactions were observed at all six dose levels. A dose response effect was obtained. With a dose increase greater than 10 mg, the duration of effect was prolonged.

Conclusion: Behavioral changes in irritability, restlessness, and sleep disturbance are associated with the ingestion of tartrazine in some children. A dose response effect was observed. (J P 1994;125:691-8)