

Do Food Additives cause hyperactivity and Behavioural problems in a population of three year olds?

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 17/09/2010	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

SPGS803

Study information

Scientific Title

Acronym

FAB

Study objectives

Do artificial food colourings and the preservative sodium benzoate affect the behaviour and activity levels of a geographically defined group of three year olds?

Secondary Questions:

1. What is the prevalence of hyperactivity and behavioural problems in a geographically defined group of three year olds?
2. What is the prevalence of atopy and allergic symptoms in a geographically defined group of three year olds?
3. To what extent do parents believe that their child's behaviour is affected by food and drink?
4. Does being atopic or hyperactive make the child's behaviour susceptible in any way to artificial food colourings and the preservative sodium benzoate?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Mental and behavioural disorders

Interventions

1. Active drink

2. Placebo

The active drink contains 20 mg total artificial food colourings (sunset yellow, tartrazine, carmoisine and ponceau 4R) and 45 mg of sodium benzoate.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

'Active drink' (contains 20 mg total artificial food colourings [sunset yellow, tartrazine, carmoisine and ponceau 4R] and 45 mg of sodium benzoate)

Primary outcome(s)

Measurement of hyperactivity and behavioural problems.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2000

Eligibility

Key inclusion criteria

Children on the Isle of Wight born between 01/09/1994 and 31/08/1996.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/07/1999

Date of final enrolment

01/03/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The David Hide Asthma and Allergy Research Centre

Newport

United Kingdom

PO30 5TG

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2004		Yes	No