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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Belinda Bateman

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

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 measure

Measurement of hyperactivity and behavioural problems.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1999

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

Age group

Child

Sex

Both

Target number of participants

1873 (added 17/09/10; see publication)

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

England

United Kingdom

Study participating centre
The David Hide Asthma and Allergy Research Centre
Newport
United Kingdom

Sponsor information

Organisation

PO30 5TG

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

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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