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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
17/09/2010

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Belinda Bateman

Contact details
The David Hide Asthma and Allergy Research Centre
St Mary's Hospital
Isle of Wight
Newport
United Kingdom
PO30 5TG
+44 (0)1983 534113
belinda.bateman@lineone.net

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

Primary study design
Interventional

Study design
Randomised controlled trial

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