ISRCTN13645495 https://doi.org/10.1186/ISRCTN13645495

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

Submission date	Recruitment status
23/01/2004	No longer recruiting
Registration date	**Overall study status**
23/01/2004	Completed
Last Edited	**Condition category**
17/09/2010	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
PO30 5TG

Sponsor information

Organisation
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