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Chronic and Acute Effects of Artificial Colourings and Preservatives on Children's Behaviour

Submission date
18/07/2005

Recruitment status
No longer recruiting

Registration date
02/08/2005

Overall study status
Completed

Last Edited
07/12/2007

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

pwh/ab/16/1/2491

Study information

Scientific Title

Acronym
FABiC - Food And Behaviour in Children

Study objectives
1. Do children show a behavioural response to the withdrawal and introduction of artificial food colourings and preservatives (AFCPs)?
2. What are the characteristics that differentiate responders to AFCPs and non-responders baseline attention deficit hyperactivity disorder (ADHD) symptom severity and/or their genotype?
3. Can any response that is found in the stage one trial be replicated in a blind acute challenge?

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)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Hyperactivity

Interventions
A within subject double blind food challenge exposure to two additive mixes and one placebo mix - all children receiving all mixtures in a randomised order

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artificial food colourings and preservatives (AFCPs)

Primary outcome measure
1. Direct observation of classroom behaviour
2. Parent and teacher ratings of hyperactive behaviour
3. Continuous performance test assessment of sustained attention

Secondary outcome measures
Sleep

Overall study start date
01/03/2005

Completion date
28/02/2007

Eligibility

Key inclusion criteria
Stage 1 - Chronic exposure - 120 three year old children and 120 eight year old children from the general population.
Stage 2 - Acute exposure - 45 eight year old children selected as being responders or non-responders in the Stage 1 challenge.

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
153 3 year-olds and 144 8/9 year-olds

Key exclusion criteria
Those on special diets.

Date of first enrolment

01/03/2005

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Research Support Office
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name
Food Standards Agency (UK) (Grant T07040)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	03/11/2007		Yes	No