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Aspartame study: Determination of the symptoms of aspartame in subjects who have reported symptoms in the past compared to controls

Submission date
10/08/2012

Recruitment status
No longer recruiting

Registration date
11/10/2012

Overall study status
Completed

Last Edited
09/09/2015

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
There is public concern over the safety of the artificial sweetener aspartame and the European Food Safety Authority has brought together an expert committee to review the evidence. The UK Food Standards Agency has suggested a small study to look at the concerns of the public on the symptoms caused by aspartame. In this study we will use questionnaires and laboratory tests to determine whether the perceived effects of aspartame can be detected in people who say they have a problem eating aspartame, compared with people who consume aspartame with no problem.

Who can participate?
People who say they have a problem eating aspartame and people who normally consume foods containing aspartame with no problem.

What does the study involve?
Participants are asked to eat a snack bar containing aspartame and a matched bar containing no aspartame at two visits one week apart. The dose of aspartame is well below the maximum recommended level.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Hull and Hull Royal Infirmary Hospital (UK).

When is the study starting and how long is it expected to run for?
February 2010 to August 2012.

Who is funding the study?
Food Standard Agency (UK).

Who is the main contact?
Professor Stephen Atkin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.5

Study information

Scientific Title
Determination of the symptoms of aspartame in subjects who have reported symptoms in the past compared to controls: a pilot double blind placebo-controlled study

Study objectives
To assess the efficacy of the necessary psychometric and biochemical methodologies to determine whether the perceived effects of aspartame can be detected in sufferers compared to non sufferers

Ethics approval required

Old ethics approval format

Ethics approval(s)
East Yorkshire & North Lincolnshire Research Ethics Committee, 30/06/2009, ref: 09/H1304/46

Study design
Double-blinded placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Safety study to assess the effect of aspartame

Interventions
75 self reported responders to aspartame and 75 normal control participants

The snack bar is to be eaten by fasting participants; they will be asked to eat 2 bars given in a double blinded and randomized order, one containing aspartame and one is aspartame free. These bars will be given to the subject one week apart. The dose of aspartame in the bar is 100mg, this is well below the Reference Daily Intake maximum recommended by EFSA of 40mg /kg bw.

Visit 1 - Full blood count (FBC), biochemical profile
Visit 2 & 3 - Insulin, Glucose, Glucagon-like peptide-1 (GLP-1), Gastric inhibitory polypeptide (GIP), biochemical profile and glucose, glucagons, Interleukins, TNF alpha and IgE, Aspartame

Intervention Type
Other

Primary outcome measure
Testing of the rigour of the study methods and design. To determine the power needed for a large scale study for the investigation of subjects with self diagnosed adverse reactions to aspartame.

Secondary outcome measures
1. To validate that the product used for the trial is optimal and fit for purpose
2. To ascertain the optimal design for the main study

3. To validate the questionnaire tools for the identification of symptoms of adverse events in individuals reporting self diagnosed adverse reactions
4. To validate the biochemical assays in individuals reporting self diagnosed adverse reaction

Overall study start date
12/02/2010

Completion date
30/08/2012

Eligibility

Key inclusion criteria
Healthy volunteers:
1. No known allergies
2. No concomitant medical condition
3. No medication

Aspartame reactors:
1. Reported effect of aspartame on ingestion
2. No allergies to other food substances

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
150 (75 normal control / 75 aspartame sensitive)

Key exclusion criteria
1. Allergies to food or medication
2. A concomitant medical condition
3. Prescription medication
4. Refusal for GP to be informed

Aspartame reactors:
1. Allergies to food or medication
2. A concomitant medical condition
3. Prescription medication
4. Refusal for GP to be informed

Date of first enrolment
12/02/2010

Date of final enrolment

30/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull York Medical School
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Research & Development Department
2nd Floor, Daisy Building
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency

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	18/03/2015		Yes	No