

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

<b>Submission date</b> 10/08/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/09/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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  
stephen.atkin@hyms.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Stephen Atkin

**Contact details**  
Hull York Medical School  
Michael White Centre for Diabetes, Endocrinology & Metabolism  
Brocklehurst Building  
Hull Royal Infirmary  
220-236 Anlaby Road  
Hull  
United Kingdom  
HU3 2RW  
+44 (0)1482 675312  
stephen.atkin@hyms.ac.uk

## 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

Castle Hill Hospital

Castle Road

Cottingham

Hull

England

United Kingdom

HU16 5JQ

+44 (0)1482 461903

james.illingworth@hey.nhs.uk

### **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?
<a href="#">Results article</a>	results	18/03/2015		Yes	No