

Brain imaging responses to food images and food in insulin resistance - intervention

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| Submission date 14/12/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 14/12/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 29/03/2018 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Obesity (being very overweight) and health problems related to obesity (including type 2 diabetes) are becoming more common, causing long-term ill health. As yet we do not understand why some people are particularly prone to weight gain and diabetes. One possibility is that people who are more prone to obesity and diabetes have a malfunction in the brain mechanisms that stop their desire to eat more after a meal. Gaining further knowledge of the way the brain controls eating will help the development of new ways to prevent and treat these diseases. This study looks at the way the brain controls appetite by using functional magnetic resonance imaging (fMRI), comparing the results from people who are "insulin resistant" and therefore at a higher risk of developing diabetes with people who are "insulin sensitive" and therefore at a lower risk of developing diabetes.

Who can participate?

Men aged between 18-65 years with a body mass index (BMI) of no more than 30 kg/m². Insulin sensitive participants should not have any family history of diabetes mellitus. Insulin resistant subjects must have first degree relatives (i.e. parent, sibling or child) with type 2 diabetes.

What does the study involve?

All participants that have been checked to see if they can take part (see <http://www.isrctn.com/ISRCTN18732138>) have a series of functional resonance brain imaging (fMRI) studies to see how insulin resistance effects the response of the brain to food. These studies are completed within four weeks. The insulin resistant volunteers are then randomly allocated to one of two groups. Those in group 1 receive insulin sensitisation therapy for three months. Those in group 2 are given a placebo for three months. These volunteers then do the same fMRI studies that they did at the beginning of the study.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

King's College Hospital NHS Trust

When is the study starting and how long is it expected to run for?
December 2010 to November 2013

Who is funding the study?
Diabetes UK

Who is the main contact?
Professor Stephanie Amiel
stephanie.amiel@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Stephanie Amiel

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9117

Study information

Scientific Title
Brain imaging responses to food images and food in insulin resistance: a single centre randomised observational treatment based case-control study

Acronym
DRN 518

Study objectives
Obesity and related health problems including type 2 diabetes are becoming more common, causing long-term ill health. As yet, it is not understood why some people are particularly prone

to weight gain and diabetes. One possibility is a malfunction in the brain mechanisms that stop our desire to eat more after a meal in people predisposed to obesity and diabetes. Gaining further knowledge of the way the brain controls eating will help the development of new ways to prevent and treat these diseases.

The project will look at the way the brain controls appetite by using functional magnetic resonance imaging (fMRI). This is a method of taking images of the brain that will allow us to see the activity of brain regions that control eating. Brain responses will be studied after eating in healthy relatives of people with diabetes, who are "insulin resistant", where the body is less responsive to insulin, a hormone normally produced by the body to control sugar (glucose) levels. These people will therefore be at higher risk of developing diabetes and obesity. They will be compared to people who are insulin sensitive, at lower risk of diabetes. The impact of treating insulin resistance on these brain responses will then be investigated. This will allow researchers to see if the brain controls eating differently in those at risk of diabetes and obesity, and whether it can be reversed. The imaging methods that are developed may also permit the early assessment of potential therapies to improve appetite control, aiding the development of new ways to prevent or treat obesity and diabetes in the future.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East London REC3 (formally King's College Hospital REC), 18/06/2010, ref: 10/H0808/47b

Study design

Single centre randomised observational treatment based case-control study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Obesity

Interventions

Both insulin sensitive and insulin resistant volunteers identified as meeting the inclusion criteria during the initial screening study (UKCRN 9515, DRN 546, ISRCTN18732138), will undergo a series of functional magnetic resonance brain imaging (fMRI) studies, to investigate the effect of insulin resistance on brain responses to food ingestion and food cues. These initial fMRI studies

will be completed within a four week period. To determine whether the effect of insulin resistance on these central responses is reversible, the insulin resistant volunteers will then be randomised to receive either placebo or insulin sensitisation therapy during a 3 month intervention period, before the fMRI studies are repeated.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Brain responses to food measured by using functional magnetic resonance imaging

Secondary outcome measures

Insulin sensitivity, measured at each functional magnetic resonance imaging scan visit

Overall study start date

01/12/2010

Completion date

01/11/2013

Eligibility**Key inclusion criteria**

All subjects (insulin sensitive and insulin resistant):

1. Men
2. Age 18 - 65 years (inclusive at time of recruitment)
3. Right-handed
4. English speaking
5. No active medical illness including diabetes mellitus
6. Body mass index (BMI) less than or equal to 30 kg/m²

Insulin sensitive subjects:

7. No family history of diabetes mellitus
8. Insulin sensitive (determined by homeostatic model assessment - insulin resistance [HOMA2-IR] less than 1.47)

Insulin resistant subjects:

9. First degree relatives of patients with type 2 diabetes mellitus
10. Insulin resistance (determined by HOMA2-IR) greater than or equal to 1.47

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned sample size: 48; UK sample size: 48

Key exclusion criteria

1. Women
2. Left handedness
3. Current or past history of significant substance abuse or eating disorders
4. Use of medication that may affect brain activity (e.g. antidepressants, anticonvulsants, antipsychotic drugs), drugs for obesity (orlistat or sibutramine) or drugs that lower glucose (e.g. metformin, sulphonylureas, thiazolidinediones, incretins or insulin)
5. Inability to understand spoken and/or written English
6. Claustrophobia (because of the small bore of the MR scanner)
7. BMI greater than 30 kg/m²
8. Contraindication to MRI (pacemaker in situ, extensive dental work, history of penetrating eye trauma, presence of surgical metal clips etc.)
9. Presence of diabetes

Date of first enrolment

01/12/2010

Date of final enrolment

01/11/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

King's College Hospital NHS Trust

London

United Kingdom

SE5 9PJ

Sponsor information

Organisation

Kings College London (KCL)

Sponsor details

Hodgkin Building
New Hunts House
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/index.aspx>

Organisation

King's College Hospital NHS Foundation Trust

Sponsor details

Denmark Hill
London
England
United Kingdom
SE5 9RS

Sponsor type

Hospital/treatment centre

Organisation

King's College London

Sponsor details**Sponsor type**

Not defined

Website

<http://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/0220mzb33>

Funder(s)**Funder type**

Charity

Funder Name

Diabetes UK

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Kings College London

Alternative Name(s)

King's College, King's College London UK, KCL, King's

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

29/03/2018: Results presented at European Association for the Study of Diabetes Annual Meeting 2013 (<https://www.easd.org/virtualmeeting/home.html#!resources/increasing-homa-ir-modulates-brain-responses-to-meal-ingestion-in-insulin-sensitive-men-a-continuous-arterial-spin-labelling-functional-magnetic-resonance-imaging-study>)

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration