ISRCTN51099878 https://doi.org/10.1186/ISRCTN51099878

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

Submission date	Recruitment status	[ ] Prospectively registered
14/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/12/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/03/2018	Nutritional, Metabolic, Endocrine	[ ] 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
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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
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. Cortraindication to MRI (pacemaker in situ, extensive dental work, history of penetrating eye trauma, precense 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