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How girls' and boys' glucose and insulin responses to high and low glycaemic index meals are different during puberty

Submission date
18/09/2016

Recruitment status
No longer recruiting

Registration date
21/09/2016

Overall study status
Completed

Last Edited
18/01/2018

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
Maintaining a blood sugar concentration of around 4.5-6 mmol/L is important for the body, especially for fuel supply to areas such as the brain. Insulin is the key hormone involved in the regulation of blood sugar, with an increase in insulin causing glucose to be stored by the body's cells lowering blood sugar levels. Evidence suggests that young people undergo a period of insulin resistance during puberty, where their body does not respond to insulin as effectively and so higher levels of insulin are needed to maintain blood sugar within a healthy range. Evidence also suggest that this response is exaggerated in girls compared to boys and may be affected by maturity. No studies to date have examined how everyday meals which differ in their glycaemic index (GI; a ranking of how a carbohydrate-containing food affects blood sugar levels) are affected by this period of insulin resistance during puberty. The aim of this study is to compare the effects of a high GI (quickly broken down during digestion, increasing blood sugar) breakfast and a low GI (minimal effect on blood sugar levels) breakfast in adolescent girls and boys.

Who can participate?
Healthy children aged 11-14 years.

What does the study involve?
Participants are allocated to eat two breakfasts in a random order, on separate days, 7 days apart. The high GI breakfast consists of cornflakes, milk, toast and margarine. The low GI breakfast consists of muesli, milk and apple. Each breakfast is matched for energy and macro nutrient (carbohydrate, protein and fat) content for each participant so it provides 1.5 g of carbohydrate per kg body mass. On each study visit before eating the breakfast and then 15, 30, 60 and 120 minutes after breakfast, a fingertip blood sample is taken and so that blood sugar and insulin levels can be measured. The results are then compared between boys and girls for the two types of breakfast.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. Charnwood College (UK)
2. Market Bosworth High School (UK)

When is the study starting and how long is it expected to run for?
September 2009 to March 2010

Who is funding the study?
Nottingham Trent University (UK)

Who is the main contact?
Dr Simon Cooper
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Study website
N/A

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Sex differences in adolescents' glycaemic and insulinaemic responses to high and low glycaemic index breakfasts

Study objectives
Girls will display a greater insulinaemic response to high and low glycaemic index meals than boys.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loughborough University Ethical Advisory Committee, 01/10/2009, ref: R09-P118

Study design
Randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

Study type(s)
Other

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
Glycaemic and insulinaemic responses

Interventions
Participants are individually, randomly allocated to a trial order using the 'ABBA' method. Participants then consumed two breakfasts in the order based upon the allocation process on two separate days spaced 7 days apart.

High GI: Breakfast consists of cornflakes with milk, with white toast and margarine
Low GI: Breakfast consists of muesli with milk and an apple

In both groups, participants are given 15 minutes to consume the breakfasts. Before eating the breakfast and then after 15, 30, 60 and 120 minutes, participants have capillary blood samples taken to test for blood glucose and plasma insulin.

Intervention Type
Other

Primary outcome measure
1. Blood glucose concentration is measured using the GOD-PAP method using capillary blood samples at baseline and 15, 30, 60 and 120 minutes following the breakfast in each trial condition
2. Plasma insulin concentration is measured using an ELISA assay on capillary blood samples at baseline and 15, 30, 60 and 120 minutes following the breakfast in each trial condition

Secondary outcome measures
Insulin resistance is measured using HOMA (Homeostatic Model Assessment), calculated using the fasting blood glucose and plasma insulin concentrations collected at baseline.

Overall study start date
01/09/2009

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Aged 11-14 years
2. Healthy

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
11 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Any condition which may make the taking of capillary blood samples problematic
2. Any food allergies or intolerances to the foods provided

Date of first enrolment
01/10/2009

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charnwood College (formerly Garendon High School)
Thorpe Hill
Loughborough
United Kingdom
LE11 4SQ

Study participating centre
Market Bosworth High School
Station Road, Back Lane
Market Bosworth
United Kingdom
CV13 0JT

Sponsor information

Organisation
Institute of Youth Sport

Sponsor details
Sir John Beckwith Centre for Sport
Loughborough University
Loughborough
England
United Kingdom
LE11 3TU

Sponsor type
University/education

Website
www.lboro.ac.uk

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
University/education

Funder Name
Nottingham Trent University

Alternative Name(s)
NTU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the findings of the study in a scientific journal, with a submission expected in September 2016.

Intention to publish date
31/07/2017

Individual participant data (IPD) sharing plan
One of the conditions of the ethical committee approval was that individual level data will not be made available due to the ethical considerations of working with young people. Therefore, this data cannot be made widely available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No