

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 21/09/2016	Overall study status Completed	
Last Edited 18/01/2018	Condition category Nutritional, Metabolic, Endocrine	

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

simon.cooper@ntu.ac.uk

Study website

N/A

Contact information

Type(s)

Scientific

Contact name

Dr Simon Cooper

Contact details

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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