# Comparison of 15% versus 5% sucrose intakes as part of a eucaloric diet in overweight/obese subjects: impact on insulin resistance, insulin secretion, postprandial glucose levels and vascular compliance

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# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Steven Hunter

#### Contact details

The Regional Centre for Endocrinology and Diabetes Royal Victoria Hospital Grosvenor Road Belfast United Kingdom BT12 6BA

# Additional identifiers

Protocol serial number RGHT000460

# Study information

#### Scientific Title

## **Study objectives**

15% sucrose intake is detrimental to insulin action when compared to 5% sucrose intake as part of a eucaloric diet in overweight/obese individuals.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Regional Ethics Committee for Northern Ireland on the 30th October 2007 (ref: HSC REC 3 - REC number 07/NIR03/93).

## Study design

Randomised cross-over trial

## Primary study design

Interventional

## Study type(s)

Quality of life

## Health condition(s) or problem(s) studied

Overweight/obesity and risk of type 2 diabetes mellitus

#### **Interventions**

Each subject will undergo two dietary intervention periods, each six weeks long separated by a four week washout period. Both diets are matched for macronutrient profile and differ in their micronutrient profile, in that one will have 5% sucrose and the other 15% sucrose content.

#### Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Sucrose

# Primary outcome(s)

Insulin resistance, assessed at the end of each six week dietary period using the euglycaemic hyperinsulinaemic glucose clamp technique.

# Key secondary outcome(s))

- 1. Glucose tolerance tests, performed at the beginning and end of each six week dietary period to assess postprandial glucose levels and insulin secretion
- 2. Plasma lipids
- 3. Vascular compliance; pulse wave analysis will be done at the beginning and end of each dietary period to assess vascular compliance

- 4. Glycaemic control
- 5. Blood pressure

## Completion date

01/08/2009

# Eligibility

# Key inclusion criteria

- 1. Healthy male and female volunteers
- 2. Overweight/obese (Body Mass Index [BMI] 25 35 kg/m^2)
- 3. Over 18 years old

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

#### Age group

Adult

# Lower age limit

18 years

#### Sex

All

# Key exclusion criteria

- 1. A history of cardiac, hepatic or renal disease
- 2. Due to the use of radioisotopes, women of child bearing age will be excluded unless they are taking effective contraceptive precautions

#### Date of first enrolment

01/11/2007

#### Date of final enrolment

01/08/2009

# Locations

#### Countries of recruitment

United Kingdom

Northern Ireland

# Study participating centre

# The Regional Centre for Endocrinology and Diabetes

Belfast United Kingdom BT12 6BA

# Sponsor information

# Organisation

Belfast Health and Social Care Trust (UK)

#### ROR

https://ror.org/02tdmfk69

# Funder(s)

# Funder type

Industry

#### Funder Name

The Sugar Bureau (UK)

#### Funder Name

Northern Ireland Research and Development Office (UK)

# **Results and Publications**

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?
Results article	results	01/05/2013		Yes	No