

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

Submission date

31/10/2007

Recruitment status

No longer recruiting

Registration date

21/02/2008

Overall study status

Completed

Last Edited

28/06/2013

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Steven Hunter

Contact details

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BT12 6BA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2007

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/m²)
3. Over 18 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

12 - 15

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

Northern Ireland

United Kingdom

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)

Sponsor details

(at the Royal Hospitals site)

Royal Victoria Hospital

Grosvenor Road

Belfast

Northern Ireland

United Kingdom

BT12 6BA

Sponsor type

Hospital/treatment centre

Website

<http://www.belfasttrust.hscni.net/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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 |