ISRCTN50808730 https://doi.org/10.1186/ISRCTN50808730

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	Recruitment status
31/10/2007	No longer recruiting
Registration date	**Overall study status**
21/02/2008	Completed
Last Edited	**Condition category**
28/06/2013	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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/m^2)
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