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Impact of High Energy Nutritional Supplement Drink (HENSD) consumed for five consecutive days on appetite, energy intake, and risk factors of cardiovascular diseases and type 2 diabetes

Submission date
10/02/2014

Recruitment status
No longer recruiting

Registration date
12/03/2014

Overall study status
Completed

Last Edited
09/02/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Our initial study found that consuming one dose of High Energy Nutritional Supplement Drink (HENSD) in the morning by young, healthy, slim women increases daily energy intake and therefore promotes positive energy balance. Consumption of a HENSD not only enhances energy intake but also modifies macronutrient composition of the diet. Both positive energy balance and change in proportion of energy provided by fat and carbohydrate are known to have impact on the way the body digests lipoproteins and glucose. Therefore, this study aims to find out how these are modified by HENSD supplementation in the evening for several days.

Who can participate?
Slim healthy women aged between 18-34 years with a body mass index of 17-20 kg/m2.

What does the study involve?
The participants will be randomly allocated to take either a HENSD or a placebo drink (a low calorie drink with the same colour, volume, flavour and texture as the HENSD) for 5 days. On day 6 the participants height, body weight and fat mass will be measured. Then participants will consume their usual breakfast and lunch and blood samples will be taken in the fasting state and at half-hourly intervals after meals. In addition, a few other parameters are measured related to energy and nutrient intake. There will then be a 7-day break during which the effects of the supplements will wear off. The participants will then switch over to take the other drink for 5 days and the measurements will be repeated.

What are the possible benefits and risks of participating?
The participants will benefit by receiving feedback on their diet, body measurements, body composition, and amount of fat, glucose and insulin in their blood. The potential risk to the participants is minor bruising during collection of blood samples. This will be minimised since all the blood samples will be collected by the main researcher who is a qualified medical doctor.

Where is the study run from?
The subjects for this study will be recruited by word of mouth and through advertisement leaflets in the campus of the University of Glasgow (UK), Yorkhill Hospital (UK) and the Royal Infirmary (UK). During the study days, participants will have to visit Human Nutrition Section, School of Medicine, College of Medical Veterinary and Life Sciences, Glasgow, UK.

When is the study starting and how long is it expected to run for?
The study started in February 2014 and is expected to be completed in June 2014.

Who is funding the study?
University of Glasgow (UK).

Who is the main contact?
Dr Dalia Malkova, Dalia.Malkova@glasgow.ac.uk
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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
Impact of High Energy Nutritional Supplement Drink (HENSD) consumed for five consecutive days on appetite, energy intake and cardiometabolic risk factors in underweight females

Study objectives
Study aims to check the hypothesis that consumption of high-energy supplements (HENSD) in the evening for several days, which is expected to increase daily energy intake and modify macro-nutrient content of the diet, has a detrimental impact on fasting and postprandial plasma triacylglycerols (TAG) responses and insulin sensitivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The College of Medical, Veterinary and Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects, University of Glasgow, Research Ethics Committee, 19/11/2012, ref: 2012084

Study design
Single-blinded randomised controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please contact s.fatima.1@research.gla.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
High Energy Nutritional Supplement Drinks

Interventions
During 5 days participants in the evening will consume:

1. HENSD (Scandishake, Chocolate, Nutricia) made up with 240 g of full fat milk, according to the manufacturer instructions (Nutricia, 2009)
2. Placebo (a low calorie drink prepared with 240 g of skimmed milk, 4 g of cocoa and two sweeteners)

The participants receive HENSD or placebo in a random order. The wash-out period is 7 days. The total duration of the intervention for each trial is 6 days, with 5 days of supplementation and day 6 of the experiment involving consumption of ad libitum breakfast and lunch and measurement of all primary and secondary outcomes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Fasting lipids, postprandial lipaemia, insulin resistance - The determination of total cholesterol, triacylglycerol, high density lipoproteins will be performed on an automated Roche Cobas Mira Plus spectrophotometric analyser (Cobas Mira Plus (ABX Diagnostics, France), by enzymatic calorimetric method using commercially available kits (ABX Pentra, Horiba ABX, France). Quantitative insulin analysis will be performed by using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (Mercodia AB, Uppsala Sweden) and plasma glucose will be analysed using a commercial assay kit (Life Sciences, Cambridge, UK) and an automated Cobas Mira biochemical analyser.
2. Energy intake and body mass - For measurement of rate of energy expenditure (EE) a ventilated hood system (Oxycon Pro, Jaeger GmbH, Hoechberg, Germany) will be used.

On day 6, the participants will be requested to come to the metabolic room at the Human Nutrition Section (School of Medicine, College of Medical Veterinary and Life Sciences, Glasgow, UK) at ~ 08:30am in a fasted state. Participant height, body weight and fat mass will be measured and fasting blood samples will be collected. Then approximately 10-15 minutes will be given to the participant to rest and acclimatize with the environment. Subsequently metabolic rate will be measured for a duration of 20 minutes. The participants will be asked to consume ad libitum buffet breakfast and lunch. Following breakfast and lunch blood samples will be collected at 30, 60, 90 and 120 minutes. Immediately at all time points at which blood samples will be collected following breakfast and lunch appetite will be measured using visual analogue scales. In addition, the rate of energy expenditure (EE) for the duration of 20 minutes will be measured at all time points after breakfast and lunch. The amount of food offered and leftover during ad libitum buffet breakfast and ad libitum buffet lunch will be recorded by the researcher.

Body height will be measured with a height measuring scale (portable stadiometer) (Seca, Leicester, UK). Body weight and fat mass will be measured to the nearest 0.01 kg using a bioelectrical impedance scale (TBF-300, TANITA, Cranlea, UK).

The energy consumed during the days prior to experimental trial and during ad libitum meals will be calculated using dietary analysis software (Windiets 2005, The Robert Gordon University, Aberdeen, Scotland, UK).

Secondary outcome measures
1. Appetite measures - appetite sensations will be measured with validated appetite questionnaires (Flint, Raben et al. 2000). Venous blood samples will be collected in 9 ml vacutainers containing EDTA and then appropriately treated with chemicals prior to preparation of plasma.
2. Metabolic rate

Overall study start date
12/02/2014

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Healthy women with body mass index of 17- 20 kg/m2
2. The participants have a stable weight for one month prior to the study
3. The participants have regular menstrual cycle

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
22

Key exclusion criteria
1. Pregnancy
2. History of eating disorder
3. History of gastrointestinal problems or surgery
4. History of some allergy
5. History of chronic illness
6. On any medication
7. On nutritional supplements
8. Following specific diet
9. Currently taking part in other research

Date of first enrolment
12/02/2014

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Human Nutrition Section, School of Medicine College of Medical, Veterinary and Life Sciences
Glasgow
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Sponsor information

Organisation
University of Glasgow (UK)

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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