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What effect does increasing the amount of dietary carbohydrate have on blood sugar in people with type 2 diabetes?

Submission date
15/11/2018

Recruitment status
No longer recruiting

Registration date
29/11/2018

Overall study status
Completed

Last Edited
20/12/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Carbohydrate is the macronutrient that causes the greatest rises in blood sugar levels after a meal. Accordingly, carbohydrate restriction has been proposed as the most effective dietary intervention for the management of type 2 diabetes. However, studies have shown only modest superiority of low-carbohydrate diets compared to high-carbohydrate diets on blood sugar. This might be because the carbohydrate intake in these studies is not low enough. A recent study showed that restricting carbohydrate to 26-40% of calories has no effect on blood sugar. Therefore, this study aims to determine how much carbohydrate should be restricted to have clinically significant effects on blood sugar.

Who can participate?
Adults aged 40-60 years old with type 2 diabetes who are otherwise healthy

What does the study involve?
All participants will receive five different "doses" of carbohydrate which are 10% of calories from carbohydrate, 15% of calories from carbohydrate, 20% of calories from carbohydrate, 25% of calories from carbohydrate and 30% of calories from carbohydrate. They receive these doses in different orders, which will be decided randomly. Blood sugar will be measured using a continuous glucose monitor which is a device which sits on the abdomen and measures blood sugar values every 5 minutes.

What are the possible benefits and risks of participating?
The possible benefit of participating is that all participants will be provided with all meals during the study. A possible risk of participating is that constipation may be a consequence of the low carbohydrate diets, but the diets are planned with vegetables and fibre to avoid this. Participants will also be advised to increase their water and non-caloric fluid intake.

Where is the study run from?
Dasman Diabetes Institute in Kuwait City (Kuwait)

When is the study starting and how long is it expected to run for?
October 2018 to February 2020

Who is funding the study?
1. The Dasman Diabetes Institute (Kuwait)
2. The Kuwait Foundation for the Advancement of Science (Kuwait)

Who is the main contact?
Dr Nicola Guess
nicola.guess@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nicola Guess

Contact details
Kings College London, Division of Nutrition and Diabetes
Room 4.13, Franklin-Wilkins Building
150, Stamford Street, London
United Kingdom
SE1 9NH

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
D-ROC2: Exploring the Dose-Response effect Of Carbohydrate restriction on glycaemia in people with type 2 diabetes

Acronym
D-ROC2

Study objectives

There will be a dose-response relationship between carbohydrate intake as a percentage of calories and glycaemia measured by CGM in people with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/01/2019, Dasman Diabetes Institute Research Ethics Committee (Office of Regulatory Affairs, P.O.Box 1180, Dasman 15462, Kuwait; +965 2224 2999; ora@dasmaninstitute.org), ref: RA HM-2018-041

Study design
Interventional within-group dose-escalation randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Current intervention as of 06/02/2020:
All diets will be provided to the participants for the duration of the study from Protein Fitness Meals in Kuwait City to ensure compliance to the dietary protocol. Participants will receive one of 5 doses of carbohydrate - 10%, 15%, 20%, 25% and 30% in randomised order. They will have a wash-out period of no less than 7 days. Protein will remain constant throughout at 15% of calories, with the fat content of the diet altering to ensure the diet remains isocaloric.
A Medtronic iPro device will be used through each dose of carbohydrate. The CGM will be placed 24 h before a person starts the "dose" to ensure the baseline glycaemia is captured. .
In addition to the primary outcome of 24-h glycaemia, an overview of glucose profiles, average glucose concentrations during specified periods (eg post-prandially only) and standardized measures of glucose control including mean amplitude of glucose excursions (MAGE) will be generated. The high blood glucose index and postprandial glucose increment will be calculated.
To ensure weight maintenance throughout the study, individual calorie requirements will be determined using validated estimates of calorie requirements by the NIH Body Weight Planner. In addition, on the day before starting the study participants will be asked to weigh themselves at home. This will then enable the participant to ensure they are maintaining their weight throughout the dietary periods. If a participant gains or loses +/- 0.5 kg on two consecutive study

visits they will be advised to reduce or increase their intake while keeping the macronutrient content of the diet constant.

Previous intervention:
All diets will be provided to the participants for the duration of the study from Protein Fitness Meals in Kuwait City to ensure compliance to the dietary protocol. Dietary carbohydrate intake will be increased in increments of 5% of calories in 7-day periods. The starting dose has been selected as 10% of calories as this "dose" of carbohydrate is known to significantly lower blood glucose (post-prandial reductions of 3-4 mmol/L even in people without type 2 diabetes). The participants will consume 10% of their calories from carbohydrate for seven days, increasing to 15% of calories for seven days, 20% of calories for seven days; 25% of calories for seven days; and 30% of calories for seven days. Protein will remain constant throughout at 15% of calories, with the fat content of the diet altering to ensure the diet remains isocaloric.
A Medtronic iPro device will be used continually (changing every 7 days) to observe changes in glucose as participants transition from normal diet (3 days) to the 10% carbohydrate diet (all seven days will be captured) and through each additional dose.
In addition to the primary outcome of 24-hour glycaemia, an overview of glucose profiles, average glucose concentrations during specified periods (eg post-prandially only) and standardized measures of glucose control including mean amplitude of glucose excursions (MAGE) will be generated. The high blood glucose index and postprandial glucose increment will be calculated.
There will be no wash-out periods.
To ensure weight maintenance throughout the study, individual calorie requirements will be determined using validated estimates of calorie requirements by the NIH Body Weight Planner. In addition, on the day before starting the study participants will be asked to weigh themselves at home. This will then enable the participant to ensure they are maintaining their weight throughout the dietary periods. If a participant gains or loses +/- 0.5 kg on two consecutive study visits they will be advised to reduce or increase their intake while keeping the macronutrient content of the diet constant.

Intervention Type
Other

Primary outcome measure
Mean 24-hour glucose concentrations over the final 4 days of each dietary period measured using CGM (Medtronic iPro) at each level of carbohydrate intake

Secondary outcome measures
1. Fasting glucose concentrations (averaged from measurements taken 2 hours before breakfast) over the final 4 days of each dietary period measured using CGM (Medtronic iPro) at each level of carbohydrate intake
2. Post-prandial glucose concentrations for 3 hours following a meal (to be identified from the glucose profiles) over the final 4 days of each dietary period measured using CGM (Medtronic iPro) at each level of carbohydrate intake
3. Mean amplitude of glucose excursions (MAGE) over the final 4 days of each dietary period measured using CGM (Medtronic iPro) at each level of carbohydrate intake
4. High blood glucose index over the final 4 days of each dietary period measured using CGM (Medtronic iPro) at each level of carbohydrate intake
5. Body weight, assessed at appointment at the baseline, and day 7 of each dietary period
6. Steps per day, assessed at the baseline, and day 7 of each dietary period measured using Daffodil HPC650 pedometer

Overall study start date
30/10/2018

Completion date
28/02/2020

Eligibility

Key inclusion criteria
1. Males and post-menopausal females
2. Aged 40-60 years
3. BMI 25-40 kg/m²
4. Reporting a stable weight for 3 months prior to study commencement
5. Able to give informed consent and willing to follow the diets as described in the telephone screening
6. Type 2 diabetes diagnosed within the last 3 years and must be diet-controlled or on metformin which will be withdrawn 2 weeks prior to starting the study

Participant type(s)
Patient

Age group
Other

Lower age limit
40 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
12

Total final enrolment
12

Key exclusion criteria
1. Type 1 or monogenic diabetes.
2. On any medication for type 2 diabetes other than metformin
3. Cancer or any other debilitating disease
4. Kidney disease, liver disease, hematologic abnormalities, congestive heart failure, or untreated thyroid disease

Date of first enrolment
01/12/2018

Date of final enrolment

31/01/2020

Locations

Countries of recruitment
Kuwait

Study participating centre
Dasman Diabetes Institute
Jasim Mohamad Al Bahar St, Al Kuwayt
Kuwait City
Kuwait
Kuwait

Sponsor information

Organisation
Dasman Diabetes Institute

Sponsor details
Jasim Mohamad Al Bahar St, Al Kuwayt
Kuwait City
Kuwait
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Sponsor type
Other

Website
http://www.dasmaninstitute.org/

ROR
https://ror.org/05tppc012

Funder(s)

Funder type
Research organisation

Funder Name
Dasman Diabetes Institute/Kuwait Foundation for the Advancement of Sciences

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 06/02/2020:
1. A peer review publication of the full glycaemic, weight, and physical activity outcomes
2. Abstract submission to the American Diabetes Association Scientific Sessions 2020

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as ethics will not allow open access.

Previous publication and dissemination plan:
1. A peer review publication of the full glycaemic, weight, and physical activity outcomes
2. Abstract submission to the American Diabetes Association Scientific Sessions 2019

IPD sharing statement
The datasets generated during and/or analysed during the current study are not expected to be made available as ethics will not allow open access

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		01/06/2021	28/09/2021	No	No
Results article		30/05/2022	20/12/2023	Yes	No