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An investigation into whether the way potato is prepared, and what it is eaten with, affects the blood glucose response to its consumption, in people with type 2 diabetes

Submission date
26/07/2021

Recruitment status
No longer recruiting

Registration date
12/08/2021

Overall study status
Completed

Last Edited
29/05/2024

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
There is existing data that demonstrates that the way potato is prepared and cooked affects the blood glucose response to its consumption, but none of this work has been undertaken in type 2 diabetes (T2D). It has been argued that work in healthy individuals can simply be “translated directly” into other patient groups, however, the blood glucose response to a food is affected by insulin sensitivity, gastrointestinal motility, gut hormone response and the absorption rate of glucose. All of these factors are likely to be different in T2D. Typically potatoes are not eaten in isolation but as part of mixed meals containing both fat and protein which can also affect the glucose response. This study aims to investigate not just the glucose response to different potato preparations eaten in normal quantities, but also in normal food patterns, in a group of people with type 2 diabetes.

Who can participate?
Males and females, aged 18-70 years, with a diagnosis of type 2 diabetes longer than 6 months.

What does the study involve?
Participants will be required to attend 12 study sessions. Each session will involve eating a potato-based meal and providing finger-prick blood samples for the next 3 hours (9 samples per visit). Each visit will be separated by at least two days.

What are the possible benefits and risks of participating?
The main benefit to the participant is that they will be provided with their own personal results at the end of the study, so they can see how their own blood glucose response varies with the different cooking methods. This will allow them to amend their own cooking practises at home in order to better control their blood glucose. There is a risk of slight bruising and discomfort to the fingertips, due to the sampling method, however this usually resolves within a day and can be minimised by correct sampling technique.

Where is the study run from?
University of Surrey (UK)

When is the study starting and how long is it expected to run for?
August 2019 to October 2022

Who is funding the study?
The Alliance for Potato Research and Education (APRE) (USA)

Who is the main contact?
Dr Tracey Robertson - Email: t.m.robertson@surrey.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291203

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49430, IRAS 291203

Study information

Scientific Title
The effect of potato form and consumption pattern on acute glycaemia in individuals with type 2 diabetes

Study objectives
1. The way potato is prepared will affect the blood glucose response to its consumption
2. The addition of protein and fat to potato prepared in different ways, will reduce both the overall blood glucose response and any differences between different potato preparations in comparison to the identical potato meals consumed in isolation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2021, London Bridge Research Ethics Committee (LHREC) (Skipton House, 80 London Road, Health Research Agency, SE1 6LH, UK; +44 (0) 207104 8202; londonbridge.rec@hra.nhs.uk), ref: 21/PR/0672

Study design
Non-randomized; Interventional; Design type: Prevention, Dietary

Primary study design
Interventional

Secondary study design
Randomised controlled 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 patient information sheet.

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

Interventions
The study will be a randomised crossover study consisting of 12 study visits per participant.

Each study visit will last approximately 4 hours. Participants will arrive in the morning after an overnight fast. They will provide a finger-prick blood sample then consume the study meal. They will continue to provide finger-prick blood samples at regular intervals for the next 3 hrs. There are 6 different study meals; each participant will consume each meal twice over the course of their 12 study mornings. Each study visit will be separated by at least 2 days.

Intervention Type
Other

Primary outcome measure
At each visit using blood test:
1. Incremental area under the 3 h glucose response curve (IAUC). Sample timepoints are 0, 15, 30, 45, 60, 75, 90, 120 and 180 min.

Secondary outcome measures
At each visit using blood test:
1. Incremental area under the 3 h insulin response curve (IAUC). Sample timepoints are 0, 15, 30, 45, 60, 75, 90, 120 and 180 min.
2. Peak glucose.
3. Peak insulin.
4. Time-to-peak glucose.
5. Time-to-peak insulin.
6. Matsuda Index.
7. Insulinogenic index.

Overall study start date
16/08/2019

Completion date
11/10/2022

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of type 2 diabetes >6 months
2. Males and females
3. Aged 18-70 years
4. Ability to understand English (to provide informed consent)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Total final enrolment

Key exclusion criteria
1. Use of insulin and GLP-1 analogues
2. History of gastroparesis or gastric surgery
3. Coeliac disease/wheat intolerance
4. Irritable bowel syndrome
5. HbA1c >75 mmol/mol
6. Pregnancy/breastfeeding
7. Excess alcohol intake
8. Glucose-lowering drug dosage adjustment within the previous month
9. Antibiotics in the last 3 months

Date of first enrolment
01/08/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
Clinical Investigation Unit (CIU)
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey

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Sponsor type
University/education

Website
http://www.surrey.ac.uk/

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Research organisation

Funder Name
Alliance for Potato Research & Education

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No