

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	<input type="checkbox"/> Prospectively registered
Registration date 12/08/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/05/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291203

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

12

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

United Kingdom

England

Study participating centre**University of Surrey**

Clinical Investigation Unit (CIU)

Guildford

United Kingdom

GU2 7XH

Sponsor information

Organisation

University of Surrey

ROR

<https://ror.org/00ks66431>

Funder(s)

Funder type

Research organisation

Funder Name

Alliance for Potato Research & Education

Results and Publications

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

[HRA research summary](#)

Details

Date created

Date added

28/06/2023

Peer reviewed?

No

Patient-facing?

No