ISRCTN13747085 https://doi.org/10.1186/ISRCTN13747085

Dietary resistant starch from peas for healthy glu

Submission date	Recruitment status	[X] Prospectively registered
11/03/2015	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/03/2015	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2024	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The hormone insulin is produced by β-cells in part of the pancreas known as the Islet of Langerhans. These β-cells can deteriorate and fail to release insulin due to age and lifestyle factors which can lead to the development of type 2 diabetes. Resistant starches are found within certain food products, particularly fruits, vegetables and whole grains, and are believed to be beneficial to β-cells. This is because the resistant starch is not digested and is instead used by bacteria within the gut. The bacteria ferment the resistant starch to produce short chain fatty acids (SCFAs), which are believed to improve β-cell function. We are investigating the effects of food products containing resistant starches found naturally in peas. The aim of this study is to see if resistant starch from peas can improve β-cell function.

Who can participate?
Patients aged 18-65 years with body mass index (BMI) of 20-35 kg/m2

What does the study involve?
Participants first meet one of the research doctors who interview them and conduct a general physical examination. Participants then undergo two separate 28-day dietary supplementation periods in a random order. In each supplementation period participants are provided with common food products (bread, soup, yoghurt, fruit juice, biscuit bars) supplemented with resistant starches or food products with no supplementation. Participants are asked to eat these food products in addition to their normal diet for 28 days. Before and at the end of each 28-day supplementation period participants attend two study visits on consecutive days at the Clinical Investigation Unit, Hammersmith Hospital to assess their β-cell function and insulin sensitivity. There is a break of 28 days between finishing the first dietary supplementation period and starting the second supplementation period.

What are the possible benefits and risks of participating?
Some of the procedures in this study, such as the recording of your weight, height and blood pressure, present no risk. Other procedures, such as taking blood samples, can cause mild discomfort. The risks of taking a blood sample include: slight discomfort when the needle is inserted and possible bruising and a localised infection. These procedures will only be carried out by experienced doctors under aseptic conditions to minimise all these risks. There are no major side effects associated with eating foods containing resistant starch; however, some people may experience mild abdominal bloating.

Where is the study run from?
Imperial College of Science, Technology and Medicine (UK)

When is the study starting and how long is it expected to run for?
April 2015 to September 2026

Who is funding the study?
Biotechnology and Biological Sciences Research Council (UK)

Who is the main contact?
Dr Katerina Petropoulou, katerina.petropoulou12@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Katerina Petropoulou

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
168400

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 18551, IRAS 168400

Study information

Scientific Title
Dietary resistant starch from peas for healthy glucose homeostasis: a randomised controlled trial

Acronym

CRESTAR

Study objectives
The aim of this trial is to develop a systematic basis for increasing the intake of resistant starch in the diet in order to protect the function of insulin-secreting pancreatic beta-cells and improve blood glucose homeostasis in an ageing population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2015, London - Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; Tel: not applicable; surrey.rec@hra.nhs.uk), ref: 15/LO/0184

Study design
Randomized; Interventional; Design type: Treatment

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Metabolic and endocrine disorders; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes)

Interventions
Added 04/07/2016:
Our study will focus on peas, as there is a range of naturally occurring variants known to contain different types of resistant starch. Participants will be provided with normal peas (control) or peas with high resistant starch content (intervention) to add to their diets for 28 days.

Intervention Type
Supplement

Primary outcome measure
Current primary outcome measures as of 04/07/2016:
Beta-cell function assessed by intravenous glucose tolerance test pre- and post 28 day intervention

Previous primary outcome measures:
Improvement in insulin sensitivity; Timepoint(s): 3 years

Secondary outcome measures
Added 04/07/2016:
1. Glucose and insulin responses assessed by meal tolerance test pre- and post 28 day intervention
2. Gastric emptying assessed by 13C ocatnoic breath test pre- and post 28 day intervention
3. Gut microbiota composition assessed from a stool sample pre- and post 28 day intervention

Overall study start date
01/04/2015

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Body mass index (BMI) of 20-35 kg/m2
2. Age between 18-65 years (inclusive)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. Weight change of = 3kg in the preceding 2 months
2. Current smokers
3. Substance abuse
4. Excess alcohol intake
5. Pregnancy
6. Diabetes
7. Cardiovascular disease
8. Cancer

9. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
10. Kidney disease
11. Liver disease
12. Pancreatitis
13. Use of medications likely to interfere with energy metabolism, appetite regulation and hormonal balance, including: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones.

Date of first enrolment
01/04/2015

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College of Science, Technology and Medicine
Du Cane Road
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the research will be published in an open-access, peer-reviewed journal. In addition we will be collaborating with patient groups and professional groups to disseminate the findings via multiple media channels such as patient association publications, print and broadcast media.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Katerina Petropoulou (katerina.petropoulou12@imperial.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications		26/10/2020	22/03/2024	Yes	No