ISRCTN18097249 https://doi.org/10.1186/ISRCTN18097249

The effect of chickpea structures on glucose response and appetite regulation

Submission date
22/01/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
A number of reports globally demonstrate the rates of obesity and type 2 diabetes continue to increase. It highlights the importance of the maintenance of an energy balance and glucose homeostasis. Chickpeas are high in resistant starches and protein, and these nutrients have been shown to stimulate gut hormone secretion that could regulate glucose homeostasis. Therefore, this study aims to investigate the impact of different chickpea tissue-structures on gut hormone secretion, thus explaining the chickpeas' influences on glucose control and satiety reported in previous studies. This project will improve understanding of the relationship among food structure ranging in processing, nutrient bioavailability and chickpea-induced release of gut hormone.

Who can participate?
People aged 18 – 65 years with a BMI of 18 – 30 kg/m²

What does the study involve?
This study is to test the physiological effects of three chickpea-based meals that different in processing and microstructures. This is a randomised crossover study therefore every participant will receive the same treatments.

What are the possible benefits and risks of participating?
Benefits: Taking part in the study will provide no direct benefit for you. The information that we get from this study will help us to better understand normal appetite regulation and may help us to better treat future patients who suffer from obesity. If any of the screening questionnaires or blood tests reveal any medical problems (e.g. diabetes, kidney or liver problems), your GP will be informed so that they can coordinate your further care, arrange any further tests, and refer you on to Hospital Doctors if necessary.
Risks: The diets consumed over the course of the study are common food items and dietary supplements. They are generally not found to be linked to any serious side effects.
Insertion of the cannula into participants' arms on each of the study visits may cause minor discomfort or superficial bruising. Serious risks associated with the insertion of the ensonetric tubes are very rare and almost negligible. These risks include bleeding, perforation or damage to the base of the skull. Minor discomfort of the back of the throat does occur in the majority of

patients and may result transiently in a sore mouth, thirst, swallowing difficulties or hoarseness. The fluoroscopy procedure will expose participants to a small dose of radiation. The mean effective dose from each nasogastric tube procedure is equivalent to 2.8 months of natural background radiation (the same amount as you would be exposed to walking around outside) and would increase the risk of inducing cancer by 0.0025% (or 1 in 40,000). The minimum number of fluoroscopy procedures that will be conducted is 3. The maximum number of fluoroscopy procedures that will be conducted is 6.

Where is the study run from?
Imperial College NIHR/Wellcome Trust Imperial Clinical Research Facility, Hammersmith Hospital, UK

When is the study starting and how long is it expected to run for?
July 2019 to August 2024

Who is funding the study?
1. Biotechnology and Biological Sciences Research Council, UK
2. National Institute for Health Research (NIHR), UK

Who is the main contact?
Dr Mingzhu Cai (public)
m.cai18@imperial.ac.uk
Prof. Gary Frost (scientific)
g.frost@imperial.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Mingzhu Cai

ORCID ID
https://orcid.org/0000-0002-1474-0224

Contact details
Commonwealth Building
Imperial College Hammersmith Campus
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)7395757128
m.cai18@imperial.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Gary Frost

ORCID ID
https://orcid.org/0000-0003-0529-6325

Contact details
Commonwealth Building
Imperial College Hammersmith Campus
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)20 8383 8037
g.frost@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
256533

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
6, IRAS 256533, CPMS 42519

Study information

Scientific Title
Determining the effect of chickpea tissue-structures on metabolic responses, satiety regulation and gut content along the entire gastrointestinal tract on healthy participants

Study objectives
Micro-structures of chickpea that are more resistant to digestion can improve glucose response and prolong appetite.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/07/2019, London-Camden and Kings-Cross Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0) 20 7104 8222; nrescommittee.london-camdenandkingscross@nhs.net), ref: 19/LO/0962

Study design
Single-centre randomised crossover nutritional-intervention study

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Digestion in healthy participants

Interventions
This study consists of one 4-day study visit and three 3-day study visits. At least one week's gap is needed. The 4-day study visit will mainly look at the upper gastro-intestine (GI) while the 3-day ones will look at the lower GI.

During each study visit, chickpeas-based meals in different structures (broken cells, intact cells, and cell clusters) will be served to participants. Then the physiological responses will be investigated:
Bloods will be taken to measure the post-prandial glucose, insulin, gut hormone and metabolites; Guts samples will be taken through a nasoenteric tube to monitor the digestive behaviours and structures breakdown; VAS will be conducted to measure subjective appetite; Urine and stool samples will be collected to measure the metabolites.

Randomisation is conducted using the website of sealed envelope: https://www.sealedenvelope.com/

Intervention Type
Other

Primary outcome measure
Appetite-regulating gut hormones measured using RIA assay in the intestinal contents that will be collected through a nasoenteric tube at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day

Secondary outcome measures
1. Circulating concentrations of glucose, insulin, and metabolites measured using ci8200 analyser enzymatic method, RIA assay, and GC-MS respectively at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day
2. Subjective measures of appetite, as assessed by Visual Analogue Scales (VAS) at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day
3. Energy intake as determined by an ad libitum meal at 240 min at each study day

Overall study start date

01/07/2019

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. Age between 18 - 65 years (inclusive)
2. Body mass index (BMI) of 18-30 kg/m²
3. Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
15

Total final enrolment
13

Key exclusion criteria
1. Abnormal ECG
2. Screening blood results outside of normal reference values
3. Weight change of ≥ 5kg in the preceding 2 months
4. Current smokers
5. History of substance abuse and/or excess alcohol intake • Pregnancy • Diabetes • Cardiovascular disease
6. Cancer
7. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
8. Kidney disease
9. Liver disease
10. Pancreatitis
11. Started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids,

antibiotics, androgens, phenytoin, erythromycin or thyroid hormones
12. Participation in a research study in the 12 week period prior to entering this study
13. Any blood donation within the 12 week period prior to entering this study

Date of first enrolment
11/02/2020

Date of final enrolment
27/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College NIHR/Wellcome Trust Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
Shepherd's Bush
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College London

Sponsor details
Joint Research Compliance Office
Imperial College London and Imperial College Healthcare NHS Trust
London
England
United Kingdom
W2 1PG
+44 (0)207 594 1872
becky.ward@imperial.ac.uk

Sponsor type
University/education

Website

http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

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
Current publication and dissemination plan as of 16/08/2023:
Some preliminary results have been published in a PhD thesis. Final results will be published in 1-2 open-access scientific journals.

Previous publication and dissemination plan:
The study results will be published in a PhD thesis and 1-2 scientific papers in peer-reviewed journals.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v7	13/09/2019	11/02/2020	No	No
HRA research summary			28/06/2023	No	No
Thesis results		01/08/2022	10/08/2023	No	No
Results article		20/06/2025	24/06/2025	Yes	No