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Effect of consumption of different legumes on blood glucose

Submission date	Recruitment status	[X] Prospectively registered
17/06/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2022	Digestive System	

Plain English summary of protocol

Background and study aims
Pulses are dry edible seeds of leguminous plants, characterised by high content of complex carbohydrate, dietary fibre, protein and micronutrient contents. Evidence suggests that their consumption may beneficially impact on blood sugar (glycaemic response) following a meal in healthy and diabetic people. However, it has been suggested that different food processing methods might impact on carbohydrate availability for digestion and therefore the glucose response.

This study aims to investigate the effect of pulse consumption such as (kidney beans and chickpeas) on the 24h glucose response, measured by continuous glucose monitoring technique. We will compare the pulses that have been prepared using different domestic cooking techniques such as (boiling, pressure cooking, canning, and legume flour pasta).

Who can participate?
Healthy male and female adults with 18-30 BMI.

What does the study involve?
Each subject will visit the research centre 4 times, each time consuming a different food in random order (3 pulse samples and white bread or potato as control). The food will be prepared by the researcher at the University of Leeds in the Food Technology Laboratory (G08, Food Science Building).

What are the possible benefits and risks of participating?
There are no direct benefits to participants but the information obtained will help to better understand the possible effect of legumes on blood glucose.
Risks of the include minor possibility of experiencing discomfort or light bleeding from finger pricks or continuous glucose monitoring device. The restriction of food intake during the three hours of the test may result in hunger but this is a short period of fasting and therefore no risk is anticipated. Participants will complete a health questionnaire to exclude individuals with a potential allergy to the test foods or any other conditions which may increase the risk of adverse effects.

Where is the study run from?
School of Food Science and Nutrition, University of Leeds, UK.

When is the study starting and how long is it expected to run for?
June 2019 to November 2019

Who is funding the study?
King Abdulaziz University, Saudi Arabia

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MEEC 18-035

Study information

Scientific Title

Effect of acute consumption of legumes with different processing on post-prandial glycaemic profile

Study objectives
The different processing methods of the different legumes will affect the post-prandial glycaemic levels

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2019, University of Leeds Research Ethics Committee (University of Leeds Leeds, LS2 9JT, UK; +44113 3431642; MEECResearchEthics@leeds.ac.uk), ref: MEEC 18-035.

Study design
Single-centre randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Current interventions as of 04/10/2019:
The study will be a randomized, cross-over dietary intervention on 25 participants. Each subject will require coming for 4 visits control, and 3 different processing (canned, pureed, and pasta) of chickpeas over a period of 2 weeks, the order of which will be randomized using a computer to assess the post-prandial and 24h glycaemic effect by using continuous glucose monitors. The food will be prepared in the food tech lab at the University of Leeds according to the procedure followed by the food lab to avoid any risk of contamination. Before a test day, participants will be asked to fast overnight, to refrain from strenuous exercise for 24 hours and to refrain from drinking alcohol during the evening before the study visit. On each visit, a cannula will be inserted in the arm of the participant for blood collection at the beginning of each visit and will be removed after 3 hours. A small blood sample will be taken from the cannula, then they will be asked to consume either freshly prepared beans or chickpeas, canned beans or chickpeas or bean or chickpeas made pasta or white wheat bread or potatoes only provided by the

researcher. They will also be asked to abstain from all foods (can drink water) during following 3 hours. After that, few blood sample will be taken by inserted cannula at 30, 60, 90, 120, 150 and 180min after eating. The procedure will be conducted on weekdays only with test food given alternatively at each session. They will be asked to answer some questionnaires related to food intake.

Previous interventions:
The study will be a randomized, cross-over dietary intervention on 25 participants. Each subject will require coming for 4 visits control, and 3 different processing (canned, pureed, and pasta) of chickpeas over a period of 2 weeks, the order of which will be randomized using a computer to assess the post-prandial and 24h glycaemic effect by using continuous glucose monitors. The food will be prepared in the food tech lab at the University of Leeds according to the procedure followed by the food lab to avoid any risk of contamination. Before a test day, participants will be asked to fast overnight, to refrain from strenuous exercise for 24 hours and to refrain from drinking alcohol during the evening before the study visit. Their blood glucose will be measured on arrival the following morning by taking blood via a finger prick test then small device for continuous glucose monitoring will be attached to their upper arm by qualified practitioner (it will remain inserted there until they finish all four visits within two weeks, instructions about it will be provided) and a blood sample will be taken. Then they will be asked to consume either pureed chickpeas, canned chickpeas or chickpeas made pasta or potatoes only provided by the researcher. They will also be asked to abstain from all foods (can drink water) during the following 3 hours. Two more blood samples will be taken at 90 min and 180 min after eating. The procedure will be conducted on weekdays only with test food given alternatively at each session. They will be asked to answer some questionnaires related to food intake.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 04/10/2019:
Post-prandial glucose peak measured by continuous glucose monitoring system at 30, 60, 90, 120, 150 and 180min after eating

Previous primary outcome measure:
Blood glucose will be measured on arrival the following morning by taking blood via a finger prick test then small device for continuous glucose monitoring will be attached to their upper arm by qualified practitioner. Two more blood sample will be taken at 90 min and 180 min after eating

Secondary outcome measures
1. Insulin and satiety hormones measured using the same blood samples collected as above.
2. Inflammatory markers measured using the same blood samples collected as above.
3. Food habits measured by the food frequency questionnaire during each visit.

Overall study start date
01/02/2018

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Aged >= 18 years
2. Healthy
3. BMI 18 - 30

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Total final enrolment
19

Key exclusion criteria
1. Regular drug therapy
2. Diabetes (fasting glucose >126 mg/dL, or anti-diabetic treatment)
3. Hypothydroidism or thyroxine treatment
4. Ill or suffer from any underlying health condition that can affect their ability to taste, smell, chew, digest or excrete of food
5. History of cancer or cancer treatment
6. Active or recently diagnosed intestinal malabsorption or disorders associated with malabsorption: Crohn’s disease, short bowel syndrome, Pancreatic insufficiency, cystic fibrosis, Tropical Sprue, whipple’s disease, chronic pancreatitis, gastrojejunostomy, surgical treatments for obesity, cholestasis, biliary atresia, parasite infections, HIV/AIDS
7. Use of medication known to cause malabsorption: tetracycline, cholestyramine, thiazide diuretics, aluminium/magnesium hydroxide, colchicine, neomycin, methotrexate, methyldopa, and allopurinol, and laxatives
8. Illegal drug use or chronic alcoholism
9. History of allergy or intolerance to any components used in the study
10. Women who are pregnant, lactating or actively trying to conceive
11. Participation in other clinical trials that may impact on outcome

Date of first enrolment
16/07/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Food Science and Nutrition
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Sponsor information

Organisation
King Abdulaziz University

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Sponsor type
University/education

ROR
https://ror.org/02ma4wv74

Funder(s)

Funder type
University/education

Funder Name
King Abdulaziz University

Alternative Name(s)
, L'université du Roi Abdulaziz, La Universidad Rey Abdulaziz, King Abdulaziz University of Saudi Arabia, KAU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

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

Intention to publish date
30/12/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/01/2022	24/01/2022	Yes	No