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Lowering the glycaemic index of white bread using a white bean extract

Submission date	Recruitment status	[_] Prospectively registered
21/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2010	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PL900E

Study information

Scientific Title
Lowering the glycaemic index of white bread using a white bean extract: an open-label crossover study

Study objectives
The hypothesis of this study was that a white bean preparation could lower the effective glycaemic index of a high glycaemic food (white bread).

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB approval was obtained from the Copernicus Group (Cary, NC) in December 2004 (ref: IHR1-04-147)

Primary study design
Interventional

Study design
Open-label six-arm crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glycaemic index measurements

Interventions
This is an open-label six-arm crossover study with 13 randomised healthy adults. Standardised testing of the glycaemic index was performed on white bread with and without the addition of the white bean preparation in several doses formulated in capsules or in powder form. The study was conducted at a single site Medicus Research Clinical Research Center, Northridge, CA, USA.

The white bean preparation was a water extract of the white kidney bean (Phaseolus vulgaris) standardised to alpha-amylase (8; 12; 15; 39) inhibiting units (Pharmachem Laboratories, Kearny, NJ). The white bread was Wonder brand (Interstate Bakeries, Kansas City, MO). Subjects reported to the study centre seven times during which they received 50 g net carbohydrates in the form of white bread with butter either by itself or with a form of extract. The test product was given at dosages of 1500 mg, 2000 mg, and 3000 mg in capsule form and 1500 mg, 2000 mg, and 3000 mg in powder form. The powder form of the test product was mixed into the butter which was spread on the bread. The capsules were taken immediately prior to the ingestion of food.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
White bean extract

Primary outcome(s)
Glycaemic index calculated according to the Food and Agriculture Organization (FAO)/World Health Organization (WHO) standard, using capillary blood glucose measurements.

Glucose measured seven times over 2 hours on each study day.

Key secondary outcome(s)
Tolerability of the white bean extract measured using 10 point Likert scales for diarrhoea, flatulence, abdominal bloating, abdominal cramping, nausea, boborygmi (bowel sounds) and soft stools.

Glucose measured seven times over 2 hours on each study day.

Completion date
01/11/2005

Eligibility

Key inclusion criteria
1. Aged between 24 and 44 years, males only
2. Body mass index (BMI) between 18 and 25 (kg/m^2)
3. Fasting glucose levels less than or equal to 100 mg/dL
4. Agreed to all study visits and procedures
5. Agreed to use appropriate forms of birth control if females of child bearing potential

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Key exclusion criteria
1. Any active eating disorders
2. Gastrointestinal illness
3. History of gastrointestinal surgery, diabetes or other endocrinological disorders

Date of first enrolment
01/04/2005

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Blvd. Suite 240
Northridge
United States of America
91325

Sponsor information

Organisation
Pharmachem Laboratories, Inc (USA)

ROR
https://ror.org/02ygftm07

Funder(s)

Funder type
Industry

Funder Name
Pharmachem Laboratories, Inc (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/10/2009		Yes	No