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

| Submission date                 | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|---------------------------------|---|--|--|--|
| 21/07/2009                      |   | ☐ Protocol                                 |  |  |
| Registration date<br>19/08/2009 | Overall study status Completed          | Statistical analysis plan                  |  |  |
|                                 |   | [X] Results                                |  |  |
| <b>Last Edited</b> 22/01/2010   | <b>Condition category</b><br>Other      | [] Individual participant data             |  |  |
| <u> </u>                        | Other                                   |  |  |  |

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

### Type(s)

Scientific

### Contact name

Dr Jay Udani

### Contact details

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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)

### Study design

Open-label six-arm crossover study

### Primary study design

Interventional

# 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              |