# Blocking carbohydrate absorption and weight loss: a clinical trial using the phase 2® brand proprietary fractionated white bean extract

| Submission date   | Recruitment status                | Prospectively registered                      |
|-------------------|-----------------------------------|---|
| 29/11/2004        | No longer recruiting              | ∐ Protocol                                    |
| Registration date | Overall study status              | Statistical analysis plan                     |
| 08/12/2004        | Completed                         | ☐ Results                                     |
| Last Edited       | Condition category                | Individual participant data                   |
| 08/09/2011        | Nutritional, Metabolic, Endocrine | <ul><li>Record updated in last year</li></ul> |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Dr Jay Udani

### Contact details

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

# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

# **Study objectives**

Not provided at time of registration

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Study type(s)

**Not Specified** 

# Health condition(s) or problem(s) studied

Overweight

### **Interventions**

After this screening period, participants were randomly allocated to receive either the Phase 2® brand proprietary fractionated white bean extract or identical placebo in a double-blind manner. Assessors and participants were blinded to group assignment.

Two people dropped out after having been randomised. One withdrew from the study before receiving any product and another withdrew after receiving product but without ingesting it or following other protocol requirements. These persons are not included in the data analysis.

Phase 2® was administered in the form of a 500 mg capsule. A capsule of identical appearance, texture, taste, and smell was used as the placebo. Participants were advised to take two capsules (1000 mg) at the beginning of breakfast and lunch each day. No other drugs, herbs, or non-prescription products for obesity were allowed during the study.

An intensive dietary intervention including personalised diet instructions and prepared food was provided. Participants in both groups were supplied with supplemental foods which met the diet parameters to facilitate compliance and to avoid having diet restrictions produce a financial burden for participants. Breakfast and lunch were provided on a daily basis and dinners were prepared along dietary guidelines by participants. They were instructed to maintain a caloric intake of 1800 calories. Additionally, they also received a personalised exercise regimen which instructed them to exercise at least one half hour, four times a week. Finally, subjects received weekly group behavioral therapy sessions in order to problem-solve personal eating issues.

# Intervention Type

Drug

### Phase

**Not Specified** 

# Drug/device/biological/vaccine name(s)

Phase 2® brand proprietary fractionated white bean extract

# Primary outcome(s)

Not provided at time of registration

# Key secondary outcome(s))

Not provided at time of registration

## Completion date

31/05/2002

# Eligibility

# Key inclusion criteria

- 1. Aged over 18 and under 40 at screening
- 2. Body Mass Index (BMI) more than or equal to 23kg/m^2 and less than 31 kg/m^2 at screening
- 3. Agreement to maintain diet, exercise and behavioral modification guidelines while participating in the study
- 4. Agreement to periodic follow-up
- 5. Females agreement to use appropriate birth control methods during the active study

### Participant type(s)

Patient

# Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

Αll

### Key exclusion criteria

- 1. Use of any drugs, herbs or other non-prescription preparations for obesity within four weeks of screening including, but not limited to, Sibutramine, Orlistat, Phen-Fen, Metabolife, diuretics etc
- 2. Abnormal electrocardiogram (EKG), Complete Blood Count (CBC), metabolic panel, or physical examination
- 3. An active eating disorder
- 4. Severe hepatic or renal disease
- 5. History of seizure, alcohol abuse, chronic malabsorption, diverticulosis or diverticulitis
- 6. Diagnosis of coronary artery disease, congestive heart failure, stroke, arrhythmia, or uncontrolled hypertension
- 7. Pregnancy or lactation
- 8. Inability to understand or follow the study protocol
- 9. Diagnosis of significant psychiatric disease or depression
- 10. Known sensitivities to the product

### Date of first enrolment

# Date of final enrolment 31/05/2002

# 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

### **ROR**

https://ror.org/02ygftm07

# Funder(s)

# Funder type

Industry

### **Funder Name**

Research Grant from Pharmachem Laboratories

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration