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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	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
01/04/2000

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

Sponsor details
265 Harrison Ave.
Kearny
United States of America
07032

Sponsor type

Not defined

ROR
https://ror.org/02ygftm07

Funder(s)

Funder type
Industry

Funder Name
Research Grant from Pharmachem Laboratories

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration