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The effect of a novel polysaccharide blend (PGX® micro-granules) on short- term weight loss and other laboratory parameters in overweight and obese adults: an observational retrospective analysis

Submission date	Recruitment status
12/04/2007	No longer recruiting
Registration date	**Overall study status**
16/10/2007	Completed
Last Edited	**Condition category**
19/07/2021	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of a novel polysaccharide blend (PGX® micro-granules) on short- term weight loss and other laboratory parameters in overweight and obese adults: an observational retrospective analysis

Study objectives
The purpose of this observational retrospective analysis is to examine the efficacy of PGX® micro-granules on weight loss, body mass index, waist circumference, waist-hip ratio, plus laboratory measurements including total and Low Density Lipoprotein (LDL) cholesterol, triglycerides, fasting insulin, fasting glucose and two hour glucose tolerance test for 14 weeks in overweight and obese adults enrolled in a voluntary community weight loss program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A research ethics review was not performed on this project as this was not intended to be a study at the outset. These were patients we worked with in the course of our clinical practice. After the weight loss clinical program, we performed a retrospective analysis of clinical outcomes.

Study design
An observational retrospective program design.

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Overweight/obesity

Interventions

Subjects gave their written consent for participation in the program and were required to attend group lectures on general health, diet, and exercise, every two weeks given by Dr Lyon for a 14 week period. During the 14 week program, volunteers were required to take up to 10 grams of PGX® micro-granules with 12 to 16 oz of water in divided doses throughout the day.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
PGX® micro-granules

Primary outcome measure
Primary outcomes measured for all participants are weight (pounds), waist and hip circumference, and percent body fat. Percent body fat was determined using bioelectrical impedance testing at baseline and every two weeks thereafter.

Secondary outcome measures
All subjects enrolled in the program were initially evaluated for High Density Lipoprotein (HDL), LDL, total cholesterol, triglycerides, fasting glucose, fasting insulin, two hour fasting insulin, and 75 gram glucose tolerance test at baseline, only those with aberrant risk factors were re-tested using the latter laboratory parameters at week 14.

Overall study start date
01/06/2005

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. 20 to 65 year of age
2. Body mass index range of approximately 23 kg/m^2 to 35 kg/m^2
3. Otherwise healthy

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
29

Total final enrolment
29

Key exclusion criteria
1. Morbid obesity
2. Major psychiatric diagnosis
3. Use of other weight loss medications such as sibutramine or ephedra

Date of first enrolment
01/06/2005

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
Canada

Study participating centre
1550 United Blvd.
Coquitlqam
Canada
V3K 6Y7

Sponsor information

Organisation
Factors Group of Nutritional Companies Inc. (Canada)

Sponsor details
1-3655 Bonneville Place
Burnaby
Canada
V3N 4S9

Sponsor type
Industry

Website
http://www.naturalfactors.com/index.asp

Funder(s)

Funder type
Industry

Funder Name
Factors Group of Nutritional Companies Inc. (Canada) - continuing education grant

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			19/07/2021	Yes	No