A double blind, placebo controlled, randomized, cross-over study to assess the effects of polydextrose on appetite suppression and its mechanisms of action in healthy women with a normal weight and overweight female participants

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The main objective is to evaluate the appetite suppressive effect of polydextrose, measured as the Energy Intake at ad libitum lunch (T=240 min) on normal weight and overweight women consuming 12.5 g of polydextrose or placebo in a low-fat yogurt as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON41091

Source
ToetsingOnline

Brief title
JZ PDX Satiety

Condition

- Appetite and general nutritional disorders

Synonym
not applicable

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: healthy female subjects, overweight, polydextrose, satiety

Outcome measures

Primary outcome

Energy, macronutrient and fiber intake from ad libitum lunch;

Appetite/satiety variables measured by VAS questionnaires: hunger,

satisfaction, fullness, prospective food consumption, and desire to eat,

Mood and well-being;

Satiety hormones: CCK, ghrelin, PYY and GLP-1

Glucose and insulin

Stomach emptying rate

Energy intake from diaries

Secondary outcome

see previous section

Study description

Background summary

Overweight and obesity are a global epidemic, which causes a rapid increase in the frequency of diabetes and cardiovascular diseases. Food ingredients that influence the mechanisms that regulate satiety may play a role in weight management. Suppression of appetite may reduce energy intake, which in return

may lead to body weight reduction. This study aims to verify the appetite suppressive effect of polydextrose in comparison to a placebo.

Study objective

The main objective is to evaluate the appetite suppressive effect of polydextrose, measured as the Energy Intake at ad libitum lunch (T=240 min) on normal weight and overweight women consuming 12.5 g of polydextrose or placebo in a low-fat yogurt as a preload (T=150 min).

Study design

This is a double blind, placebo controlled, randomized, cross-over study.

Study burden and risks

The test product is a normal food ingredient, not posing any risk to the health of the volunteers.
The blood collection may cause discomfort or bruising. Occasionally, fainting or an infection at the blood sampling site can occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Healthy female participants aged 20-45 years inclusive;
2.BMI: 20-30 kg/m2 inclusive;
3.Written consent regarding participation after full information regarding all details of the study;
4.Normal Dutch eating habits (consuming mostly three main meals per day; used to eat bread for lunch);

Exclusion criteria

1.Pregnancy;
2.On-going or recent treatment for diabetes, hypertension, coronary heart disease, psychiatric conditions, inflammatory chronic disease - rheumatoid arthritis, Crohn Disease, ulcerous colitis, chronic constipation, eating disorders, or any disease condition which interferes with ADME of the investigational product;
3.Reported postmenopausal;
4.Having menstruation problems, e.g. PCOS;
5.Reported to be on a slimming diet or other dietary treatment (currently or during last two months, like vegetarian diet, lactose restricted diet etc.);
6.Aversion towards products (yoghurt) provided in the study;
7.On-going use of any slimming preparations;
8.Any kind of dysfunction of digestive tract, food allergy, chronic constipation, recent/actual gastroenteritis;
9.Restrained eaters
10.Participants consuming more than 23 g of dietary fiber per day
11.Smoker in the last 3 months;
12.Heavy coffee drinkers (more than 6 cups a day);
13.High level of physical activity
14.Heavy alcohol consumers

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2014
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48027.056.14