Digestive tolerance of several doses of a sugar replacing product

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Objective: The objective of the study is to evaluate the digestive tolerance of three dosages of a sugar replacing product consumed daily for two weeks versus a reference

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30925

Source
ToetsingOnline

Brief title
Digestive tolerance of Sweetwell X

Condition

- Other condition

Synonym
obesitas reduction; metabolic disorder

Health condition

uiteindelijk doel preventie van overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Sweetwell N.V.
Source(s) of monetary or material Support: Sweetwell N.V.;Antwerpen;Belgie

Intervention

Keyword: Clinical trial, Digestive tolerance, GI-tract complaints, Sugar replacement

Outcome measures

Primary outcome

Main study parameters/endpoints: The tolerance of the products will be evaluated by questionnaires filled in directly following a two week period of consumption of each of the products at home. Also the reported GI complaints will be evaluated by the daily filled in diary, in which they register the consumption of the study products, the frequency and appearance of defecations and any other remarks or complaints such as flatulence.

Secondary outcome

Not applicable

Study description

Background summary

Rationale: Daily sugar intake has dramatically increased over the past decades (> 30%) and is directly associated with obesitas and health complaints. To decrease obesitas replacement of sugar with a product having a comparable sweetness but a much lower caloric value is a good alternative. In this study the tolerance of a low caloric sugar replacing product is investigated in human volunteers. The tolerance of this product in 3 different daily doses consumed for a period of 2 weeks will be evaluated versus a reference. The tolerance will be evaluated using questionnaires related to GI complaints.

Study objective

Objective: The objective of the study is to evaluate the digestive tolerance of three dosages of a sugar replacing product consumed daily for two weeks versus a reference

Study design

Study design: Randomized (BMI and age; gender in design), reference-controlled, double-blind, 4-way cross over design

Intervention

Intervention: The following 4 treatments will be used in the study:
- Treatment 1: a low dose of product X (30 g/d):
- Treatment 2: a middle dose of product X (50 g/d)
- Treatment 3: a high dose of product X (70 g/d)
- Treatment 4: reference (table top sugar) (40 g/d)
All treatments will be supplied to the subjects in processed foods (e.g., cake)

Subjects will consume the study products daily at home for a period of 2 weeks. Evaluation of the GI complaints will be performed using a questionnaire directly following the 2 weeks of consumption. Subjects will keep a diary, in which they register the daily consumption of the study products, the frequency and appearance of defecations and any other remarks or complaints.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Consumption of sugar within the general population is irrespective of age and a daily habit. The selected number of subjects in this study is 1) based on experience with previous studies performed at TNO and 2) to detect a change in response of 1 category in flatulence between treatments. Based on 1) the fact that all individual ingredients are on the market for a long time and that each is numbered and listed or affirmed as GRAS (Generally Recognized as Safe) by the FDA and 2) the limited duration of consumption of the product (2 weeks) it is highly unlikely to expect any serious complaint due to the treatments. Only very minor or negligible effects such as increased flatulence are expected to occur. Therefore, the risks for subjects participating in the study are negligible and the body burden is minimal.

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

Healthy as assessed by
* the TNO health and lifestyle questionnaire
* results of the pre-study laboratory test
2 Females and males, age * 20 and * 60 years at Day 01 of the study
3 Body Mass Index (BMI) * 18 - * 32 kg/m2
4 Having a regular defecation frequency
5 Regular and normal Dutch eating habits (consuming mostly three main meals including breakfast) and snacks as assessed by the questionnaire on health and lifestyle
6 Daily user of table top sugar in coffee, tea, yoghurt, etc

Exclusion criteria

1 Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
2 Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
3 Having a history of medical or surgical events that may significantly affect the study outcome, including metabolic or endocrine disease, especially Diabetes type I or II,
4 Alcohol consumption > 28 units/week (for men) or > 21 units/week (for women)
5 Reported food allergy or sensitivity (chocolate, wheat, dairy products, egg, nuts, etc)

6 Having gastro-intestinal complaints regularly (stomach upsets, diarrhoea, constipation, flatulence, abdominal colic, etc)
7 Reported unexplained weight loss or weight gain of > 2 kg in the month prior to pre-study screening
8 Use of antibiotics within 1 month, or laxatives, more then once, within 1 week before day 01 of the study
9 Reported slimming or medically prescribed diet
10 Pregnant or lactating or wishing to became pregnant in the period of the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2007
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL19052.028.07