A double blind, placebo-controlled, cross-over randomized trial to determine the possibile effect of specially bred cumcmbers (Trees) on glucose homeostasis.

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To investigate the effect of specially bred snack cucumbers (Trees) intended for human consumption on glucose homeostasis in comparison to common snack cucumbers (Cucumis Sativus) after OGTT in obese individuals.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34157

Source
ToetsingOnline

Brief title
Effect of Trees cucumber on glucose homeostasis

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
glucose homeostasis

Research involving
Human

Sponsors and support

Primary sponsor: Sportfruit B.V
Source(s) of monetary or material Support: Food inducstry: Sportfruit B.V.

Intervention

Keyword: cucumber, glucose, obesity, Trigonelline, Type 2 diabetes

Outcome measures

Primary outcome

The main parameters will be glucose, insulin and glucagon (measured regularly

over 3.5 hrs during the OGTT).

Secondary outcome

not applicable

Study description

Background summary

In this study the possible effect of a specially bred cucumber for human consumption on the bloodglucose level will be investigated in people withe obesity.
In healthy people the body regulates the glucose homeastasis with insuline. In type 2 diabetes, the body is not able to keep the glucose levels in good balance, because the body does not responde well enough /or there is too little insuline in the body. Without good working insuline the body is not capable to get rid to the glucose in the blood. The blood glucose levels stay too high. Besides, the fat metabolism is not functioning well. For people with diabetes having a special diet can be of value for the glucose balance in the blood. In animal research it appears that eating cucumbers can positively effect the glucose levels in blood. Sportfruit B.V. in Poeldijk has bred special cucumbers that might lower the blood glucose levels in the blood better than normal cucumber do.. In case Trees cucumbers should have a positive effect on glucose homeostasis, the consumption of these cucumbers might have an added value in combination with a T2DM diet.

Study objective

To investigate the effect of specially bred snack cucumbers (Trees) intended for human consumption on glucose homeostasis in comparison to common snack cucumbers (Cucumis Sativus) after OGTT in obese individuals.

Study design

double blind, placebo-controlled, cross-over randomized trial to determine the possible effect of specially bred cucumbers (Trees) on glucose homeostasis.

Intervention

Eating 5 specially bred (active) and normal snack (placebo) cucumbers.
Drinking of 300 ml glucose water for the oral glucose tolerance test

Study burden and risks

The potential risk for the subjects associated with consumption of the specially bred snack cucumber (Trees) is minimal. Although it is expected by the sponsor that consumption of the specially bred snack cucumber will cause a decrease of the glucose level and that this effect is more prominent compared to the effect caused by a common snack cucumber (placebo), this difference is not expected to result in a potential risk for the subject. The consumption of the specially bred cucumbers (Trees) is considered safe.

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

Male or female subjects, age 18 to 65 , inclusive. Body Mass Index (BMI) 28 and above

Exclusion criteria

Any clinically significant abnormality as determined by medical history taking and physical examinations obtained during the screening visit that in the opinion of the investigator would interfere with the study objectives or compromise subject safety;
Clinically relevant abnormal laboratory results, ECG, vital signs at screening that in the opinion of the investigator would interfere with the study objectives or compromise subject safety;

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2011
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO Date:	09-12-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL34589.058.10