Assessment of Mass Balance of Orally Administered [14C] Tagatose in Healthy Volunteers Using a Microtracer Approach

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To determine the mass balans after ingestion of a single dose of tagatose, a low-glycaemic sugar, in healthy volunteers.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53253

Source
ToetsingOnline

Brief title
TrueCal

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Obesity;Overweight

Health condition

Metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Bonumose;Inc.

Intervention

Keyword: Carbohydrates, Metabolism, Stable isotopes

Outcome measures

Primary outcome

72h mass balance following 14C-tagatose ingestion.

Secondary outcome

Secondary endpoints: content of 14C-labelled metabolites in carbohydrate

metabolism pathways, whole-body substrate (carbohydrate and lipid) oxidation.

Study description

Background summary

Worldwide almost 40% of the adult population is overweight (including >10% obese), and more than 350 million children (up to the age of 19) are overweight. This causes severe problems, socially, psychologically but also medically, where people may have an increased risk for various life-threatening diseases. The caloric value of carbohydrates is an important parameter in our daily nutrition. In the battle against overweight, it is of key to understand which nutrition contributes to what extent in caloric intake. The caloric intake is calculated based on the energy in covalent bonds and the assumption that all energy is absorbed and used by the body. However, this often overestimates the caloric value of a compound. A low-glycaemic sugar, i.e. tagatose, has been developed to support weight management, yet its true caloric value is currently unknown.

Study objective

To determine the mass balans after ingestion of a single dose of tagatose, a low-glycaemic sugar, in healthy volunteers.

Study design

Single group design

Intervention

A single test day during which participants will orally ingest a dietary supplement containing 14C-labelled tagatose, followed by a 72-hour test period during which all urine and faeces will be collected, as well as repeated sampling of blood and expired air, as well as indirect calorimetry measurements.

Study burden and risks

Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma. Tagatose ingestion might lead to gastro-intestinal discomfort. During the run-in period participants will consume commercially available Bomunose, which is safe for human consumption. The radioactive labelled tagatose that will be consumed orally on the test day is produced under sterile conditions according to GMP standards and completely safe for human consumption.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 18-65 years old healthy female and male using contraception during and for 3 months after the study
- BMI 18.5-25 kg/m2
- Must be willing and able to communicate and participate in the whole study, including consumption of tagatose and meals offered during study conduct
- Must have regular bowel movements (i.e. average stool production of >=1 and <=3 stools per day)Must usually eat 3 meals per day (i.e. breakfast, lunch and dinner)

Exclusion criteria

- Diabetes (Type 1, Type 2, or genetic form of diabetes) - Any diagnosed cardiovascular (heart) disease or high blood pressure (>=140 mmHg systolic and/or >=90 mmHg diastolic) - History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastro-intestinal disease, immunodeficiency, endocrine, neurological or psychiatric disorders - Any diagnosed respiratory disease, such as COPD or asthma - Any previous motor disorders or disorders in muscle and/or lipid metabolism - Known severe kidney problems - Presence of an ulcer in the stomach or gut and/or strong history of indigestion - Recent or chronic history of diarrhoea - Known anaemia - A personal or family history of thrombosis (clots), epilepsy, seizures, or schizophrenia. - Regular use of dietary supplements (>3 times per week) - Chronic use of any prescribed or over the counter pharmaceuticals (excluding oral contraceptives and contraceptive devices)History of any drug or alcohol abuse in the past two years - A confirmed positive alcohol breath test at screening or admission - Drug use - Claustrophobia - Subjects who are on a weight loss diet or following a high calorific/high protein diet in order to gain weight - Subjects with functional constipation - Any known food allergies or intolerances to the 14 major food allergens (celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, tree nuts, peanuts, sesame seeds, soybeans, sulphur dioxide and sulphites) or history of a malabsorption syndrome including coeliac disease - Subjects who have regular gastrointestinal complaints including abdominal pain, stomach upsets and borborygmi or known or suspected irritable bowel syndrome - Currently taking part in other scientific research - Having received a product with 14C in the past 12 months - Pregnant or breastfeeding - Smoking or having used

nicotin-containing products in the 6 months prior to the study. - Subjects who have taken antibiotics within the 60 days prior to the adaptation period. - Currently involved in a structured progressive resistance training programme (>3 times per week) - Sedentary lifestyle as assessed using the International Physical Activity Questionnaire [IPAQ]. - Employed or undertaking a thesis or internship at the department of Human and Animal Physiology - Unable to give consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2024
Enrollment:	8
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-11-2023
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	NL84060.028.23