An Open-Label, Non-Randomised Study to Assess Calorific Value and Mass Balance of Orally Administered [14C]-labeled test product in Healthy Adult Subjects Using a Microtracer Approach

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23266

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Not Applicable

Sponsors and support

Primary sponsor: TNO on behalf of industry
Source(s) of monetary or material Support: Industrial funding

Intervention

Outcome measures

Primary outcome

caloric value of the test product

Secondary outcome

adsorption and metabolism of test product
mass balance of test product
routes and rates of elimination of test product in urine, feces and expired air
characterize metabolite profiles of test product in urine, feces and plasma

Study description

Background summary

12 healthy males and females will receive a single microtracer dose of the [14C]-labeled testproduct after a 7-day adaptation phase with unlabeled test poduct. After the 14C-labeled dose, 14C activity will be monitored in plasma, urine, feces and expired air to assess mass balance and caloric value of the test product.

Study objective

Not Applicable

Study design

not sure what to enter

Intervention

10 days intake of test product, of which 1 day 14C-labeled test product

Contacts

Public
TNO
Rianne de Ligt

+31 88 86 65064
Scientific
TNO
Rianne de Ligt

+31 88 86 65064

Eligibility criteria

Inclusion criteria

1.Healthy males or healthy females of non-childbearing potential
2.Age 18 to 65 years of age at the time of signing informed consent
3.Body mass index (BMI) of 18.0 to 29.9 kg/m2 (inclusive)
4.Must be willing and able to communicate and participate in the whole study, including consumption of allulose and meals offered during study conduct
5.Must have regular bowel movements (ie average stool production of ≥1 and ≤3 stools per day)
6.Must understand the requirements of the study and provide written informed consent
7.Must agree to adhere to the contraception requirements defined
8.Must usually eat 3 meals per day (ie breakfast, lunch and dinner)
9.Must be affiliated to a social security scheme (ie have a National Insurance number)

Exclusion criteria

1.Subjects who have received any investigational medicinal product in a clinical research study within the 90 days prior to Day 1
2.Subjects who are study site employees, or immediate family members of a study site or sponsor employee
3.History of any drug or alcohol abuse in the past 2 years
4.Regular alcohol consumption in males >21 units per week and females >14 units per week (1 unit = ½ pint beer, or a 25 mL shot of 40% spirit, 1.5 to 2 Units = 125 mL glass of wine, depending on type)
5.A confirmed positive alcohol breath test at screening or admission
6.Current smokers and those who have smoked within the last 6 months. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission
7.Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 6 months
8.Females of childbearing potential including those who are pregnant or lactating (all female subjects must have a negative urine pregnancy test). A woman is considered of childbearing potential unless she is permanently sterile (hysterectomy, bilateral salpingectomy and bilateral oophorectomy), surgically sterilised (by tubal ligation or equivalent) or is postmenopausal (had no menses for 12 months without an alternative medical cause and a serum follicle-stimulating hormone [FSH] concentration ≥40 IU/L)
9.Radiation exposure, including that from the present study, excluding background radiation but including diagnostic x-rays and other medical exposures, exceeding

5 mSv in the last 12 months or 10 mSv in the last 5 years. No occupationally exposed worker, as defined in the Ionising Radiation Regulations 2017, shall participate in the study
10.Subjects who have been enrolled in an absorption, distribution, metabolism and excretion (ADME) study in the last 12 months prior to [14C]-allulose administration
11.Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening
12.Clinically significant abnormal biochemistry, haematology or urinalysis as judged by the investigator
13.Positive drugs of abuse test result or alcohol breath test at screening or admission
14.Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) results
15.Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance of <90 mL/min using the Cockcroft-Gault equation
16.History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastrointestinal disease, immunodeficiency, endocrine, neurological or psychiatric disorder, as judged by the investigator
17.Subjects who have claustrophobia
18.Subjects who are on a weight loss diet or following a high calorific/high protein diet in order to gain weight.
19.Subjects who have diabetes and/or impaired glucose tolerance
20.Subjects with functional constipation
21.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
22.Subjects who have regular gastrointestinal complaints including abdominal pain, stomach upsets and borborygmi or known or suspected irritable bowel syndrome
23.Subjects who have liquid stools at least 1 day per week
24.Subjects who have taken antibiotics within the 60 days prior to the adaptation phase
25.Subjects who have taken in the 15 days prior to the adaptation phase, any drugs, food supplements or any food presented commercially as containing substances, bacteria or yeasts likely to have an effect on gastrointestinal comfort, in particular on intestinal transit, flatulence or abdominal pains (eg probiotics, macrobiotics, L. acidophilus or bifidus bacteria)
26.Subjects who are taking, or have taken, any prescribed or over-the-counter drug (other than 4 g of paracetamol per day or HRT) or herbal remedies in the 14 days before first allulose administration (ie the adaptation period).
Exceptions may apply on a case by case basis, if considered not to interfere with the objectives of the study, as agreed by the PI and sponsor’s medical monitor
27.Subjects following chronic medical treatment, including anti-cholinergic, anti-emetic, antihistamine, anti-parkinsonian, anti-psychotic, antacid containing aluminium, analgesic, antagonist H2 receptors, opioid and narcotic, laxative or anti-diarrheal
28.Presence or history of clinically significant allergy requiring treatment, as judged by the investigator. Hay fever is allowed unless it is active
29.Donation or loss of greater than 400 mL of blood within the previous 3 months
30.Subjects with a high physical and sporting practice (defined as more than 5 h per

week, as assessed using the International Physical Activity Questionnaire [IPAQ]
31.Subjects who are under legal protection or deprived of rights following administrative or judicial decision
32.Failure to satisfy the investigator of fitness to participate for any other reason

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	21-10-2019
Enrollment:	12
Type:	Unknown

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	21-10-2019
Application type:	First submission

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
NTR-new	NL8101
Other	South Central - Oxford C Research Ethics Committee : 266652

Study results