Beschikbaarheid van uridine in het bloed van gezonde ouderen na eenmalige inname van een nucleotide en een alternatief ingrediënt.

No registrations found.

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

Summary

ID

NL-OMON24695

Source
Nationaal Trial Register

Brief title
BUMP

Health condition

Bioequivalence

Sponsors and support

Primary sponsor: Nutricia Research B.V., Utrecht, The Netherlands
Source(s) of monetary or material Support: Nutricia Research B.V., Utrecht, The Netherlands

Intervention

Outcome measures

Primary outcome

The primary outcome parameters in this study are Urd AUC [ìmol/L*min] and Cmax [ìmol/L] (product B versus A).

Secondary outcome

The secondary outcome parameters in this study are Urd AUC [ìmol/L*min] and Cmax [ìmol/L], Tmax [min] and t½ AUC [min] , Urd AUC [ìmol/L*min], Cmax [ìmol/L], Tmax [min] and t½ AUC [min].

Study description

Background summary

Background of the study:

In this study it will be investigated whether equimolar dosages of a nucleotide and an alternative ingredient will produce bioequivalent Urd plasma levels.

In this study healthy older adults are requested to consume 5 different study products. Each subject will visit the site 5 times and at every visit they will consume 1 of the 5 products after which a series of blood samples will be taken.

Study objective

To investigate whether uridine (Urd) area under the curve (AUC) and Cmax of product B is equivalent to the Urd AUC and Cmax of product A

Study design

Time points of the outcome: Study visit 1-5

Intervention

After an overnight fast, subjects will ingest one dosage of one of the five study products at each study visit (except during screening).

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy volunteers

2. Age 60 years or older

3. BMI from 20 through 30 kg/m2

Exclusion criteria

1. Any condition that may interfere with the definition ‘healthy volunteer’ according to the investigator, with special attention to the presence of liver and renal disease, diabetes mellitus, Alzheimer, diarrhea, obstipation and known severe weight loss (> 3 kg in last 3 months)

2. Any gastrointestinal (GI) disease or surgery that interferes with GI function

3. (History of) any cancer with the exception of basal cell carcinoma

4. Any sign of inflammation in the last 7 days prior to Visit 1

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2015
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-07-2015
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	NL5149
NTR-old	NTR5289
Other	Nutricia Research : Alz.1.P/E

Study results

Summary results
NA