A pilot study to explore the bioavailability of UMP enriched products in healthy volunteers

Published: 08-04-2011
Last updated: 27-04-2024

In this pilot study, the time course of the increase in blood plasma levels of uridine after single intake of UMP and UMP-enriched products will be explored in healthy volunteers. Five intervention groups will be studied; three intervention groups...

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

Summary

ID

NL-OMON36006

Source
ToetsingOnline

Brief title
UMP Pilot Study

Condition

- Other condition

Synonym
Uridine bioavailability, uridine blood levels

Health condition

Uridine bloedbeeld na uridine monofosfaat inname

Research involving
Human

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research

Intervention

Keyword: Bioavailability, Uridine, Uridine monophosphate

Outcome measures

Primary outcome

Changes in blood plasma levels of uridine over time, following single intake of

study product.

Secondary outcome

N.a.

Study description

Background summary

Uridine monophosphate (UMP) is a nucleotide that is a normal constituent of Ribonucleic acid (RNA), the molecules responsible for the proteins in the human body. RNA is present in all living cells and therefore in the human diet. Foods rich in RNA, such as sardines, yeast and some organ meats (like liver) will provide significant quantities of UMP. Upon digestion of UMP-containing food, UMP is hydrolysed to uridine by splitting off the phosphate group. Uridine is a normal metabolite in the cells of plants and animals and therefore also present in daily diet.

This exploratory study is an initial investigation that may generate information (e.g. the influence of UMP dosage on blood uridine levels, the most appropriate timing of blood sampling after intake of UMP enriched products in order to detect blood uridine levels) that will be valuable for the development of new nutritional product concepts (e.g. to reduce ingredient costs) and for the design of a larger powered randomised prospective clinical study, in which subjects will take UMP-enriched products for longer duration and in which (blood) biomarkers will be studied more extensively.
Due to the exploratory nature of the study and the absence of information with which to calculate the required group-size, no sample size calculation was done

for this study.

Study objective

In this pilot study, the time course of the increase in blood plasma levels of uridine after single intake of UMP and UMP-enriched products will be explored in healthy volunteers. Five intervention groups will be studied; three intervention groups will receive the multi-nutrient product containing different UMP dosages. The fourth intervention group will receive a UMP supplement and the control group will receive a multi-nutrient product without UMP.

Study design

This will be an open, placebo controlled study. The study duration per subject is 1 day. A total of 25 subjects will be enrolled in 1 study site in the Netherlands.

Intervention

All subjects will undergo a single intake of 125ml of the allocated study product during the study visit, and have blood sampled to determine uridine levels.

Study burden and risks

There are no known undesirable effects after intake of the study product. Of the study procedures, blood sampling may cause bruising, pain and stiffness, infection and flebitis.

Contacts

Public
Danone Research - Centre for Specialised Nutrition

Postbus 7005
6700 CA Wageningen
NL
Scientific
Danone Research - Centre for Specialised Nutrition

Postbus 7005
6700 CA Wageningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Male
-Age 50-70 years, inclusive
-BMI 18- 28kg/m2, inclusive
-Written informed consent

Exclusion criteria

-Any condition that may interfere with the definition *healthy volunteer* according to the investigator, with special attention to the presence of liver disease, bowel disease, diarrhea and catabolism (unintended recent weight loss)
-Heavy exercise like long-distance running one week prior to the study day
-The use of RNA rich nutritional supplements (such as yeast) within a period of one month prior to the start of the study
-Unable to adhere to protocol instructions
-Alcohol or drug abuse in the opinion of the investigator
-Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements
-Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL35909.072.11