Vitamin B6 study

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21970

Source
NTR

Health condition

pharmacokinetics, pyridoxine, pyridoxal-5'-phosphate

Sponsors and support

Primary sponsor: Maastricht University, MUMC
Source(s) of monetary or material Support: Natuurproducten Nederland (NPN)

Intervention

Outcome measures

Primary outcome

plasma pyridoxine concentration during 4 h after the first inake (pharmacokinetics, AUC), and at days 3 and 7 of the study

Secondary outcome

vitamin B6 vitamers and metabolites such as pyridoxal, pyridoxal-5'-phospate, pyridoxamine, 4-pyridoxic acid

Study description

Background summary

In this study the pharmacokinetics of 50 mg pyridoxal-5'-phosphate after oral intake by adult, healthy volunteers, and after daily supplementation with 50 mg during 3 and 7 days plasma B6 vitamers will be determined. This will be compared to daily intake of 50 mg of pyridoxine. Plasma concentrations of pyridoxine and other relevant B6 vitamers will be analysed.

Study objective

Supplementation with pyridoxine-5'-phosphate will not lead to an increase in plasma concentrations of pyridoxine

Study design

day 1: before intake, and 30 min, 60 min, 90 min, 120 min, 150 min, 180 min, 210 min and 240 min after intake

day 3

day 7

Intervention

daily intake of 50 mg of pyridoxal-s'-phosphate or 50 mg pyridoxine (active control) during 7 days

Contacts

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Eligibility criteria

Inclusion criteria

healthy, adults, both male and female, aged between 20 and 50 years with normal liver and kidney function, with normal BMI (between 19 and 25), and able to come to the research laboratory on 3 specified occasions within a one week period

Exclusion criteria

use of medication (with the exception of oral contraceptives), use of vitamin supplements during the past 6 months, detectable plasma level of pyridoxine, non-normal liver and kidney functions, BMI <19 or >25, alcohol consumption > 2 drinks/day

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	12
Type:	Actual

Ethics review

Not applicable

Application type: Not applicable

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	NL6105
NTR-old	NTR6446
Other	METC163051 : Universiteit Maastricht

Study results