A pharmacokinetic study of pyridoxal-5*-phosphate and pyrixodine

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45563

Source
ToetsingOnline

Brief title
Vitamin B6 study

Condition

- Other condition

Synonym
Uptake and metabolism of different forms of vitamin B6

Health condition

onderzoek naar opname en omzetting van pyridoxal-5'-fosfaat (farmacokinetiek)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Branche organisatie (bedrijf),Branche organisatie: Natuurproducten Nederland (NPN)

Intervention

Keyword: pharmacokinetics, Pyridoxal-5'-phosphate, pyridoxine

Outcome measures

Primary outcome

Using LC-MS-QTOF plasma concentrations of pyridoxine (PN) will be measured

Secondary outcome

Plasma concentrations of other B6 vitamers and metabolites: pyridoxal (PL),

pyridoxamine (PM), and the phosphorylated derivative pyridoxal 5*- phosphate

(PLP) and 4-Pyridoxinic acid (PA).

Study description

Background summary

Vitamin B6 supplementation has been found to induce neurotoxic effects (neuropathies). Animal models and recent in vitro studies in human neuronal cells indicated that the toxicity of vitamin B6 is specifically limited to one vitamer, i.e. pyridoxine (PN). Other vitamers, pyridoxal (PL), pyridoxal-5*-phosphate (PLP) and pyridoxamine (PM) did not induce toxic effects. Moreover, in vitro studies indicated that neurotoxicity of PN was reversed when PLP is administered simultaneously (Vrolijk et al., manuscript submitted, appendix 1). Currently, most vitamin supplements contain PN, but based on its neurotoxicity it appears preferable to use one of the other vitamers. This implies the assumption that the other vitamers will not induce increased plasma levels of PN, thereby greatly reducing the risk of developing neuropathies. It is not yet investigated whether the use of PLP-containing supplements can lead to increased plasma levels of PN.

Study objective

The aim of this study is to compare the pharmacokinetics of pyridoxal-5'-phosphate (PLP) and pyridoxine (PN) immediately after administration of a dose of 50 mg. In addition, plasma levels of B6 vitamers after three and seven days intake of 50 mg/day of either PLP or PN will be detemined.

Study design

Using a double blind randomized design, pharmacokinetics of 50 mg pyridoxal-5'-phosphate (PLP) and 50 mg pyridoxine (PN) will be followed during 4 hours after administration to healthy adult males and females. Every 30 min. venous blood will be sampled (iv-canule) for analysis of plasma levels of PN and other B6 vitamers using LC-MS-QTOF. In addition, after 3 and after 7 days (1 week) daily administration of either 50 mg PY or 50 mg PLP venous blood will be sampled by venapuncture for analysis of plasma levels of PN and other B6 vitamers.

Intervention

This study is a pharmacokinetic study in which healthy adults will daily receive 50 mg pyridoxal-5'-phosphate (PLP) or 50 mg pyridoxine (PN) during 1 week.

Study burden and risks

Participants of this study will receive 50 mg pyridoxal-5'-phophate (PLP) or 50 mg pyridoxine (PN) daily during one week (capsules) and venous blood samples will be taken on specific occasions: during screening for measurement of liver and kidney functions; during the pharmacokinetic study 9 venous blood samples of 5 ml (iv-canule) will be collected and after 3 and 7 days of supplementation a venous blood sample of 5 ml will be collected by venapuncture; a total of 50 ml venous blood will be sampled within 1 week. The risks involved are considered minimal and limited to potential problems that may occur venous blood sampling such as the development of hematomas. The daily supplementation with 50 mg of either PLP or PN during one week is too short to induce neurologic problems or neurotoxic effects. Results of this study will provide information that contributes to the save use of vitamin B6 supplements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2017
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL60198.068.16