

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

Published: 03-05-2017

Last updated: 11-04-2024

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...

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Approved WMO        |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | Other condition     |
| <b>Study type</b>            | 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 determined.

## **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'-phosphate (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 safe use of vitamin B6 supplements.

## **Contacts**

### **Public**

Universiteit Maastricht

Universiteitssingel 50

Maastricht 6229 ER  
NL  
**Scientific**  
Universiteit Maastricht

Universiteitssingel 50  
Maastricht 6229 ER  
NL

## 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

CCMO

### ID

NL60198.068.16