# Post-Treatment Effects of Dipyridamole On Nucleoside Transport Inhibition

Published: 18-01-2010
Last updated: 02-05-2024

Explore 4 week post-treatment effect of seven day administration of dipyridamole on nucleoside transport inhibition.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34866

**Source**
ToetsingOnline

**Brief title**
Post-treatment dipyridamole

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
Atherosclerosis, Ischemia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Pharmacology-Toxicology
**Source(s) of monetary or material Support:** Ministerie van OC&W,ZONMw

### Intervention

**Keyword:** Dipyridamole, Nucleosdie transport inhibition

## Outcome measures

### Primary outcome

Comparison of nucleoside uptake inhibition before, during (day 7), and after

(day 14, 21, 28, and 35) treatment with dipyridamole between actively treated

an control individuals at 35 days after start of the study (28 days after

cessation of treatment in actively treated subjects).

### Secondary outcome

plasma and whole blood dipyridamole concentration

# Study description

### Background summary

Preclinical evidence and a couple of human in-vivo studies have confirmed that nucleoside transport inhibitors such as dipyridamole enhance tolerance against IR-injury. Recently we have shown a protective effect of one week oral treatment with dipyridamole (200 mg, slow release, twice daily) in a forearm model of ischemia-reperfusion injury using Annexin A5 targeting as a marker of injury. In a separate follow-up randomised double-blind placebo-controlled cross-over experiment we observed a protection by dipyridamole that persisted even 4 weeks after cessation of dipyridamole treatment. This study aims to explore a potential explanation for this intriguing observation.
We hypothesize that dipyridamole accumulates in cell membranes and inhibits the nucleoside transporter in these membranes for a prolonged time even after plasma dipyridamole levels are below limits of detection.

### Study objective

Explore 4 week post-treatment effect of seven day administration of dipyridamole on nucleoside transport inhibition.

### Study design

placebo-controlled trial with open-label design.

### Intervention

treatment with either dipyridamole slow release 200 mg twice daily or no treatment during 7 days with subsequent 4 week follow-up after cessation of the treatment.

### Study burden and risks

Screening: medical history, physical examination, ECG, capillary glucose measurement.
Burden: 6x venous blood collection (120 ml in total)
Risks: side effects of dipyridamole treatment (headache and dyspepsia are most common), all reversible upon cessation of treatment.

## Contacts

**Public**
Selecteer

P.O. Box 9101
6500 HB Nijmegen
NL
**Scientific**
Selecteer

P.O. Box 9101
6500 HB Nijmegen
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

## Inclusion criteria

Healthy volunteers
Age 18-50
Written informed consent

## Exclusion criteria

Smoking
History of any cardiovascular disease
Asthma
Hypertension (in supine position: systole>140 mm Hg, diastole>90 mmHg)
Diabetes mellitus (fasting glucose >7.0 mmol/L or random glucose>11.0 mmol/L)
Concomitant use of medication
Alcohol or drug abuse
Women without appropriate anticonception
Participation to any drug-investigation during the previous 60 days as checked with VIP check

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-03-2010 |
| Enrollment: | 14 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |

| | |
|---|---|
| Brand name: | Persantin |
| Generic name: | Dipyridamole |
| Registration: | Yes - NL outside intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 18-01-2010 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 09-03-2010 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 |
|---|---|
| EudraCT | EUCTR2010-018338-39-NL |
| CCMO | NL31291.091.10 |