# Comparative study of pharmacokinetics of amlodipine besilate oral liquid and tablets in healthy Dutch volunteers

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The aim of this study is to assess and compare the pharmacokinetic parameters of the newly developed amlodipine besilate oral liquid 0,5 mg/ml with commercial Norvasc 5 mg tablets. The secondary objective is to assess the taste of the oral liquid.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular hypertensive disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36940

**Source**
ToetsingOnline

**Brief title**
Pharmacokinetics of amlodipine besilate oral liquid and tablets

### Condition

- Vascular hypertensive disorders

**Synonym**
high blood pressure, Hypertension

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** Amlodipine, Liquid, Pharmacokinetics, Tablet

## Outcome measures

### Primary outcome

The pharmacokinetic parameters Cmax, tmax, AUC0-72, AUC* of amlodipine besilate

oral liquid 0,5 mg/ml and Norvasc tablets 5 mg will be assessed.

### Secondary outcome

Secondary, the taste of the amlodipine besilate oral liquid 0,5 mg/ml will to

be determined using a questionnaire.

# Study description

### Background summary

Amlodipine is prescribed off-label for paediatric patients, but there is no safe, efficacious and appropriate paediatric formulation available. Therefore, an appropriate amlodipine besilate oral liquid 0,5 mg/ml is developed. In order to establish safety and efficacy of this formulation, the pharmacokinetics of the new oral liquid is compared with commercial available tablets in healthy volunteers.

### Study objective

The aim of this study is to assess and compare the pharmacokinetic parameters of the newly developed amlodipine besilate oral liquid 0,5 mg/ml with commercial Norvasc 5 mg tablets. The secondary objective is to assess the taste of the oral liquid.

### Study design

The study is conducted as an open-label, single-dose, two-sequence, two-period crossover design and will be performed at the Erasmus Medical Centre.

### Intervention

All participants will be randomly assigned to receive a single dose of Norvasc tablets 5 mg or 5 mg of amlodipine besilate oral liquid 0,5 mg/ml and after a two-week washout period the other formulation will be administered.

**Study burden and risks**

Each period of this study, participants are exposed to amlodipine, a common drug used for treatment of hypertension in adults. Since the safety and efficacy of amlodipine are extensively studied, the occurrence of serious side effects is expected to be rare. After intake of amlodipine, 14 hour period of hospitalization of participants is necessary to study the absorption phase accurately. At baseline and 0,5, 1, 1,5, 2, 2,5, 3, 4, 6, 8, 10, 12, 24, 48 and 72 hours post dose blood samples will be drawn. For safety reasons, blood pressure and heart rate will be monitored at baseline and 1, 3, 6, 8, 10, 12, 24, 48 and 72 hours post dose. Furthermore, subjects need to fill in a questionnaire to screen on good health and for assessing the taste of the investigational product. The possible burden of hospitalization, blood sampling and blood pressure monitoring subjects can experience, are offset with a financial compensation.

# 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

•Subject is healthy
•Subject is Caucasian
•Age is between 18-55 years
•Body Mass Index (BMI) is between 19-25
•Written informed consent

## Exclusion criteria

•Sitting blood pressure lower than 120 mmHg systolic and/or 80 mmHg diastolic in resting conditions
•Use of medication, both medicines on prescription and over-the-counter medicines, excluding contraceptives
•Subject is familiar with one of the contra-indications of amlodipine: hypersensitivity to dihydropyridine derivatives, severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle (e.g. aortic stenosis), hemodynamically unstable heart failure after acute myocardial infarction
•Allergy for one of the substances of both formulations
•Pregnancy
•Smoking
•Subject has history of alcohol or drug abuse

# Study design

## Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-03-2013 |
| Enrollment: | 12 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | - |
| Generic name: | Amlodipine oral liquid 0,5 mg/ml (as besilate) |
| Product type: | Medicine |
| Brand name: | Norvasc 5 mg tablets |
| Generic name: | Amlodipine besilate 5 mg tablets |
| Registration: | Yes - NL intended use |

## Ethics review

Approved WMO

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|---|---|
| Date: | 19-11-2012 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

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|---|---|
| Date: | 04-02-2013 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

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|---|---|
| Date: | 24-06-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

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|---|---|
| Date: | 02-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | EUCTR2012-004065-41-NL |
| CCMO | NL42509.078.12 |