Pharmacokinetic and pharmacodynamic properties of amlodipine oral liquid in the pediatric population

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

Summary

ID

NL-OMON41645

Source
ToetsingOnline

Brief title
PK-PD of amlodipine in children

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, Children, Oral liquid, PK-PD

Outcome measures

Primary outcome

The primary aim of this study is to characterize the pharmacokinetic parameters

clearance, volume of distribution, and absorption rate constant of amlodipine.

Secondary outcome

•The safety of amlodipine oral solution 0.5 mg/ml.

•The effect of the once and twice daily dosing regimen of amlodipine on the

mean SBP and DBP and amlodipine plasma concentrations.

•The taste of amlodipine oral solution 0.5 mg/ml using VAS.

•The preference of formulation of children and their parents using a

questionnaire including ease of administration and patient acceptance. .

Study description

Background summary

Amlodipine is commercially available as fixed-dosage tablets which do often not meet pediatric requirements like dose flexibility and ease of administration. Therefore, we developed a well-validated oral solution for amlodipine. Because of the extensive use of amlodipine among pediatric patients, additional information is necessary to adequately define the safety, efficacy and pharmacokinetic properties of the new formulation in children.

Study objective

The primary objective of this study is to characterize the pharmacokinetic properties of amlodipine using the newly developed amlodipine oral solution 0.5 mg/ml in patients with chronic kidney diseases (CKD) and/or hypertension aged 6 months to <12 years using a population pharmacokinetic study design. The secondary objective is to study the efficacy, safety and patient acceptability

of the investigational product.

Study design

The study will be conducted as an one-sequence, open-label, multi-dose study design

Intervention

All children will receive amlodipine oral solution 0.5 mg/ml in the same dosage as their current amlodipine treatment.

Study burden and risks

During this study, 3 blood samples will be drawn during the steady-state phase of the IMP using different sampling windows. Blood sampling will be combined as much as possible with standard health care. Also blood pressure will be measured once during the steady-state phase, using an oscillometric or 24-hour ambulatory blood pressure monitoring device, depending on the ability and willingness of the child. Because the IMP is administered with therapeutic intent to a study population which is already used to amlodipine, the possible risks of the IMP are expected to be negligible. Despite the burden of the study procedures on the study population, all procedures are outweighed against the future benefits of the IMP for the pediatric population, including well-established safety, efficacy, pharmacokinetic properties and patient acceptability.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age between 6 months and 12 years, signed consent from the parent or legal assent, ongoing treatment with amlodipine at the same dosage for at least 2 weeks, no anticipated change in use of amlodipine or other antihypertensive medication

Exclusion criteria

Concomitant treatment with another investigational drug within 1 month prior to study entry, transient, unstable, malignant, or accelerated hypertension, poor vascular access, history of noncompliance, allergy to one of the compounds of the investigational product, or one of the contraindications of amlodipine use (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), renal transplant within 4 months before inclusion.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	Amlodipine oral solution 0.5 mg/ml (as besilate)

Ethics review

Approved WMO Date:	26-05-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2016

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

ID: 24405
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-005323-17-NL
CCMO	NL47653.078.14
Other	NTR 47653
OMON	NL-OMON24405