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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23706

Source
Nationaal Trial Register

Brief title
Comparison of the pharmacokinetics of amlodipine besilate oral liquid and tablets

Health condition

Pharmacokinetics, hypertension, amlodipine besilate, oral liquid. Farmacokinetiek, hypertensie, amlodipine besilaat, orale drank.

Sponsors and support

Primary sponsor: Erasmus Medical Centre
es Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands
Phone: +31(0) 10-7040704
Source(s) of monetary or material Support: ZonMW
Laan van Nieuw Oost-Indie 334, 2593 CE The Hague, The Netherlands
Phone: +31(0) 70-3495111, Fax: +31(0) 70-3495100,
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Intervention

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

N/A

Study objective

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 design

All pharmacokinetic parameters will be evaluated after completion of the study. The taste of amlodipine besilate oral liquid 0,5 mg/ml will be evaluated by the subjects directly after intake using a questionnaire. The questionnaires will be evaluated by the investigators after completion of the study.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subject is healthy;

2. Subject is Caucasian;

3. Age is between 18-55 years;

4. Body Mass Index (BMI) is between 19-25;

5. Written informed consent.

Exclusion criteria

1. Sitting blood pressure lower than 120 mmHg systolic and/or 80 mmHg diastolic in resting conditions;

2. Use of medication, both medicines on prescription and over-the-counter medicines, excluding contraceptives;

3. 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;

4. Allergy for one of the substances of both formulations;

5. Pregnancy;

6. Smoking;

7. Subject has history of alcohol or drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	30-10-2012
Application type:	First submission

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
NTR-new	NL3520
NTR-old	NTR3682
Other	EudraCT : 2012-004065-41
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A