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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23706

Bron
Nationaal Trial Register

Verkorte titel
Comparison of the pharmacokinetics of amlodipine besilate oral liquid and tablets

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Centre
es Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands
Phone: +31(0) 10-7040704
Overige ondersteuning: ZonMW
Laan van Nieuw Oost-Indie 334, 2593 CE The Hague, The Netherlands
Phone: +31(0) 70-3495111, Fax: +31(0) 70-3495100,
E-mail: info@zonmw.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3520
NTR-old	NTR3682
Ander register	EudraCT : 2012-004065-41
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A