A randomized, double-blind, parallel group study to evaluate metabolic effects of LCZ696 and amlodipine in obese hypertensive subjects: the CLCZ696B2207 study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON40044

Source
ToetsingOnline

Brief title
The CLCZ696B2207 study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders

Synonym
Insulin sensitivity, metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: Hypertension, LCZ696, Lipolysis, Obesity

Outcome measures

Primary outcome

insulin sensitivity (Hyperinsuline Euglycemische Glucose Clamp (HEGC))

Secondary outcome

Secundairy reseach variabilities are:

subcutaneous adipose tissue lipolysis (assesed by microdialysis), oxidative

metabolism (assessed by indirect calorimetry) and tolerability of the

medication in obese hypertensive subjects.

Study description

Background summary

A lot of people suffer from obesity nowadays. It is known that obesity increases the possibilities to develop conitions like hypertension, coronary heart diseases and Diabetes Mellitus type 2 (DM type 2). All these conditions can have a negative effect on the metabolism.
LCZ696 is a newly developed medicine to treat hypertension and by its specific mechanisms it does not only lower the blood pressure, but it can also have some positive influences on the glucose- and fatmetabolism. This may lower the possibilities of developing coronary heart diseases and DM type 2.
People who suffer from hypertension or heartdiseases could have benificial effects by the use of LCZ696.
During a treatment period of 8 weeks with LCZ696 or amlodipine, the effects on insulin sensitivity, subcutaneous adipose tissue lipolysis and oxidative metabolism will be investigated in obese people with hypertension.

Study objective

The objective of this study is to investigate what the effects of LCZ696 or amlodipine are on insulin sensitivity as assessed by hyperinsulinemic euglycemic glucose clamp (HEGC) after 8 weeks of treatment. Furthermore, the effects on subcutaneous adipose tissue lipolysis (assesed by microdialysis), oxidative metabolism (assessed by indirect calorimetry) and tolerability of LCZ696 and amlodipine in obese hypertensive subjects will be measured.

Study design

Randomised, dubbel blind, parallel group intervention study

Intervention

Studiesubjects will be treated with LCZ696 (400 mg QD 1x per day) or amlodipine (10 mg QD 1x per day) during 8 weeks.

Study burden and risks

After the screening (in which the medical questionnaire will be discussed, blood and urine will be collected to determine pregnancy, alcohol- and drug use) the subjects need to come to the university 8 more times during 12 weeks (total time investment: 24 hours).
During the first visit (1 hour) a general medical examination, a ECG and an exercise test (on a cycle ergometer) will be taken. During visit 2 and 6 (6 hours), again a general medical examination and a ECG will be taken. furthermore, the insulin sensitivity will be measured by a Hyperinsulinemic Euglycemic Glucose Clamp (HEGC). During visit 3 and 7 (4,5 hours) a microdialysis will be performed together with a indirect calorimetry measurement and a adipose tissue biopsy will be taken. On visit 4 and 5 (1 hour) and visit 8 (0,5 hour) (control visits), again a general medical examination and a ECG will be taken. During all visits, the bodylength, bodyweigth, bloodpressure and hartbeat will be measured and on every visit there will be taken a bloodsample.

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

Obese people (>= 18 years old) with mild to moderate essential hypertension with non-childbearing potential

Exclusion criteria

use of other medication, pregnancy, lactating women, history of angioedema, heavy hypertention (grade 3 of the WHO classification)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Amlodipin
Generic name:	Amlodipin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	LCZ696
Generic name:	LCZ696

Ethics review

Approved WMO Date:	17-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-10-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	02-11-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-03-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-11-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2012-002606-40-NL
ClinicalTrials.gov	NCT01631864
CCMO	NL41639.068.12

Study results

Date completed:	05-07-2013

Actual enrolment: 28

Summary results
Trial is onging in other countries