Effect of Olmesartan Medoxomil on arterial stiffness and thickness in subjects with metabolic syndrome.

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to investigate in a descriptive way the dose-dependent effect of Olmesartan Medoxomil 20mg, 40mg en 80mg on arterial stiffness.

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

Summary

ID

NL-OMON35439

Source
ToetsingOnline

Brief title
Effect OM arterial stiffness, thickness with metabolic syndrome

Condition

- Vascular hypertensive disorders

Synonym
arterial stiffness and thickness, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Daiichi Sankyo Europe
Source(s) of monetary or material Support: pharmaceutisch bedrijf

Intervention

Keyword: arterial stiffness and thickness, metabolic syndrome, olmesartan medoxomil

Outcome measures

Primary outcome

to investigate in a descriptive way the dose-dependent effect of Olmesartan

Medoxomil 20mg, 40mg and 80mg on arterial stiffness assessed by:

• The change from baseline in carotid-femoral Pulse Wave Velocity (PWV) after

52 weeks of double-blind treatment

• The change from baseline in carotid-femoral PWV, after adjustment for change

from baseline in Mean Blood Pressure (MBP) after 52 weeks of double-blind

treatment

Secondary outcome

To investigate in a descriptive way the dose-dependent effect of Olmesartan

Medoxomil 20mg, 40mg and 80mg:

• The change from baseline in carotid-femoral Pulse Wave Velocity (PWV) after

24 weeks of double-blind treatment

• The change from baseline in carotid-femoral PWV, after adjustment for change

from baseline in Mean Blood Pressure (MBP) after 24 weeks of double-blind

treatment

• On Blood Pressure (BP) lowering, assessed by conventional BP measurement and

24h Ambulatory BP Measurement (24h-ABPM) after 52 and 24 weeks of double-blind

treatment

• On central Pulse Pressure (PP) and Augmentation Index (AI) after 52 and 24

weeks of double-blind treatment

• On common carotid stiffness, Intima-Media Thickness (IMT), and internal

diameter after 52 and 24 weeks of double-blind treatment.

Study description

Background summary

Olmesartan Medoxomil (OM) is an angiotensin II receptor antagonist developed for administration by the oral route. It is a competitive and selective blocker of the angiotensin II receptor subtype AT1.
OM in the form of 20 en 40 mg tablets have a proven clinical value in the the treatment of hypertension; both the 20 and 40 mg tablets are registered products in the European Union.
The current protocol is being conducted to evaluate the efficacy and safety of 3 doses of OM (20, 40 and 80 mg, in a forced titration period) on arterial stiffness and thickness in subjects with metabolic syndrome.
Patients who suffer from metabolic syndrome will gain benefit from the use of OM since the angiotensin II receptor slows down the factors that believe to have an influence on arterial stiffness, which is a characteristic of metabolic syndrome.
These patients will also benefit from the effect of the angiotensin II suppression of the arterial stiffness due to the synergetic interaction between angiotensine II en the insulin-activated conductivity in the muscular system

Study objective

to investigate in a descriptive way the dose-dependent effect of Olmesartan Medoxomil 20mg, 40mg en 80mg on arterial stiffness.

Study design

This is a Phase 3b, multi-centre, double-blind, randomized, parallel-group study, in which subjects will be assigned into three treatment groups and receive either OM 20 mg, OM 40 mg, or OM 80 mg, once a day (o.d.) for 1 year, in a forced titration design. Each group will receive OM 20 mg at baseline. After one month, two-third of subjects will switch to OM 40 mg. After another month, one-third of subjects will switch to OM 80 mg.

Intervention

1 tablet (OM 20 mg, or OM 40 mg or OM 80 mg) per day, for 1 year.

Study burden and risks

- the risk of hypotension (too low blood pressure) will be monitored and if necessary a dose down-titration will be performed.
Down-titration can only be performed once, afterwards the patient will be followed-up and is withdrawn from the trial.
- by confirmed hypertension during the trial, the subject might be excluded from the study, if this is judged necessary for the subject's safety by the investigator.

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

- Age >= 18 and <= 75 years
- Hypertension and metabolic syndrome defined, according to the ATP III/ IDF 2005 and ESH/ESC 2007 definitions with modifications;
see Amended Protocol Version NL-1.0 page 25

Exclusion criteria

- Pregnant or lactating female;
- Type 1 and type 2 diabetes;
- *High range* mild hypertension;
- Moderate, severe, or resistant hypertension;
- Secondary hypertension of any aetiology;
- Kidney function impairment;
see protocol page 25 + see Substantial Amendment 1, page 6 of 9 + Substantial Amendment the Netherlands-specific 1, page 5 of 7 + Amended Protocol Version NL-1.0 page 26

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-10-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-01-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-10-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-11-2009
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-07-2010
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	EUCTR2007-003131-23-NL
ClinicalTrials.gov	NCT00676845
CCMO	NL23231.068.08