Trial Description

Title

Sevicontrol-1: Efficacy and safety of a fixed combination of olmesartan 40 mg / amlodipine 10 mg in patients with insufficiently controlled hypertension under monotherapy with candesartan 32 mg - an open phase IIIb trial

Trial Acronym

Sevicontrol-1

URL of the trial

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Brief Summary in Lay Language

We want to find out whether a recently introduced combination of two blood pressure lowering agents (olmesartan and amlodipine) has a better blood pressure lowering effect than a single active substance. In addition we want to find out whether there is a difference in the changes in blood pressure over the course of a day depending on the time when the medications are taken (in the morning or at night). Male and female patients over 18 years of age may participate.

Brief Summary in Scientific Language

Proof of a significant lowering in blood pressur after six weeks therapy with a fixed combination of 40 mg olmesartan and 10 mg amlodipine compared to a monotherapy with 32 mg candesartan. Proof of an improved dipping-profile after a further six weeks of therapy with the fixed combination when time of intake is switched from morning to evening.

Organizational Data

- DRKS-ID: **DRKS00003272**
- Date of Registration in DRKS: **2012/01/04**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17/2011 , Ethikkommission bei der Ärztekammer Niedersachsen**

Secondary IDs

- EudraCT-Number: **2011-004235-31**
- BfArM-No.: **4037689**

Health condition or Problem studied

- ICD10: **I10.90 - [generalization I10: Essential (primary) hypertension]**

Interventions/Observational Groups

- Arm 1: **candesartan 16 mg tablets p. o. for 14 days (morning), then candesartan 32 mg tablets for 28 day (morning)s, then olmesartan/amlodipine 40/5 mg tablets for 14 days (morning), then olmesartan/amlodipine 40/10 mg tablets for 28 days (morning), then olmesartan/amlodipine 40/10 mg tablets for 42 days (evening)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

After 6 weeks therapy with a fixed combination of olmesartan and amlodipine compared to monotherapy with candesartan: change in ABPM mean daytime systolic values and change in systolic OPM.

ABPM measurements to be performed at the beginning and end of each intervention step.

Secondary Outcome

change in diastolic OPM, change in systolic and diastolic ABPM night mean values, 24 h mean values and diastolic day mean value. Distribution of patients over the four dipper types. Comparison of OPM and ABPM with regard to achievement of target bp values. Efficacy and safety of the fixed combination of olmesartan 40 mg/amlodipine 10 mg.

ABPM measurements to be performed at the beginning and end of each intervention step.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/27**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

essential hypertension, i. e. systolic OPM >=140 mmHg at screening and >=160 mmHg after two weeks wash-out

Exclusion criteria

- **systolic office bp > 180 mm Hg at screening visit**
- **known hypertensive retinopathy GIII or IV**
- **recent (< 4 weeks ago) myocardial infarction or indication for coronary or peripheral revascularisation**
- **type I diabetes or poorly controlled (HbA1c >= 8) type II diabetes**
- **chronic heart failure NYHA III or IV**
- **prior stroke or TIA**
- **creatinine clearance < 60 ml/min or condition after kidney transplant**
- **moderately or severely impaired liver function (ALT or AST or bilirubin more than double normal value)**
- **women of childbearing potential without highly effective contraception, pregnant or breastfeeding women**

- **concomitant therapy with lithium**
- **hemodynamically relevant mitral or aortic valve stenosis (>= II°) or hypertrophic obstructive cardiomyopathy**
- **concomitant therapy with strong CYP3A4 inhibitors or inductors**
- **african patients**
- **concomitant severe psychiatric condition that might impair proper intake of study medication**
- **life expectancy < 6 months**
- **night shift workers**
- **known other mandatory indication for treatment with antihypertensive medications**

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/09/25**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*