

**MeES/05/Neb-EnD/001 (NEMENDAS)**

**Comparison of the effects of nebivolol versus metoprolol succinate on endothelial function and large artery stiffness**

**This study has completed the enrolment of patients**

**Sponsor:** OU Berlin-Chemie Menarini Eesti

**Intervention:** Nebivolol 5 mg and Metoprolol 50-100 mg

**Condition:** Mild to moderate essential hypertension

**Study type & design:** parallel group, randomized, double-blind, active control, phase IV study  
Main criteria for inclusion: Patients with mild to moderate essential hypertension (systolic BP 140-179 mmHg and diastolic BP 90-109 mmHg) Male and female patients aged 30-65 years, newly diagnosed untreated patients or previously diagnosed patients who were without treatment at least two weeks prior to screening

**Main criteria for exclusion Concomitant medication:** ACE inhibitors, cyclic antidepressants, MAO inhibitors, corticosteroids Diabetes I or II type (fasting venous plasma glucose > 6.4 mmol/l) Bronchial asthma and chronic obstructive airway disease Body mass index > 30 kg/m Ischaemic

heart disease (III, IV stage, Canadian Cardiovascular Society) Clinically relevant heart failure (NYHA class II - IV Clinically relevant valve disease (physical examination) Arrhythmias and conduction disturbances, requiring therapy, sinus bradycardia at rest < 50 l/min, sick sinus syndrome, AV -block stage II - III Secondary hypertension (urea >8.3 mmol/l, creatinine >120 µmol/l (males), >103 µmol/l (females), TSH > 4.0mIU/l, free T4 > 27 pmol/l) Clinically relevant atherosclerotic disease of lower extremities, Acute inflammation (according to CRP > 10mg/l) Hypercholesterolemia (> 6,5 mmol/l) Allergic reaction to β-blockers Pregnant or breast-feeding women History of hepatic, renal, metabolic or endocrine diseases Smoking > 10 cigarettes per day Alcohol consumption > 7 drinks per week (drink = 0,33 l beer, 120 ml wine or 30 ml strong alcoholic drink). The patient has had surgery or disease of the gastrointestinal tract which, in the opinion of the investigator, may influence the absorption or elimination of the study drug The patient has a severe organic disorder that may interfere with the absorption, pharmacokinetics, or elimination of the study medication. The patient has a comorbid condition that would be expected to result in death during the trial period (e.g., terminal cancer, AIDS) The patient has chronic psychoses or behavioural conditions that would limit the ability of the patient to comply with the requirements of this study The patient has known hypersensitivity to Nebivolol, Metoprolol or hydrochlorothiazide related compounds, Patient enrolled in another clinical trial.