

**BCBe/04/Neb-Pao/087**

**Effects of Nebivolol on the walking distance in patients with essential hypertension and peripheral arterial occlusive disease(PAOD)Fontaine's stage II- A randomized, double blind, multicenter,active substance controlled clinical trial phase III**

**The study has been completed.**

**Results will be soon available in the "Results" section.**

**Sponsor:** Berlin Chemie AG

**Intervention:** Nebivolol 5 mg, HCTZ (hydrochlorothiazide) 25 mg

**Condition:** Patients with essential hypertension and PAOD Fontaine stage II(a+b)

**Study type & design:** Randomized, double-blind, multicenter, active substance controlled clinical trial phase IV

**Main criteria for inclusion:**

Subjects of 40 years to 75 years PAOD Fontaine's stage II with:

- a history of typical intermittent claudication for at least 6 months with documented lesions by duplex sonography or angiography within the last 36 months prior to inclusion,
- actual proven PAD by objective means such as haemodynamics and non-invasive imaging or angiography,
- a history of (> 1 month before study inclusion) previous peripheral (lower extremity) vascular intervention such as surgical endarterectomy, by pass grafting or aortic abdominal aneurysm repair or PTA with or without stenting is allowed,
- an ankle-brachial pressure index (ABPI) of the worse leg < 0.90 and/or systolic ankle pressure > 70 mmHg,

**Main criteria for exclusion:**

- PAD with rest pain or leg ulcer or gangrene (Fontaine stage III or IV resp. critical limb ischemia (CLI): systolic ankle pressure  $\leq$  50-70 mmHg or systolic toe pressure  $\leq$  30-40 mmHg or - transcutaneous partial oxygen pressure (tcpO<sub>2</sub>)  $\leq$  10-20 %).
- Any concomitant disease limiting the exercise capacity of the patient (e.g. but not limited to: angina pectoris, heart failure, respiratory disease, orthopaedic disease, neurological disorder)
- Cardiogenic Shock
- Heart failure NYHA class III or IV,
- Sick-sinus-syndrome including heart blocks (SA node) and/or AV block 2nd and 3rd degree and/or significant arrhythmia and/or bradycardia < 50 bpm,
- Hypotension with systolic blood pressure < 100 mmHg.