

OLM/CLIN/I-12/03

Efficacy and Safety of Olmesartan in elderly patients with mild to moderate hypertension

This study has completed the enrolment of patients

Sponsor: Malesci Istituto Farmacologico S.p.A. / Laboratori Guidotti S.p.A.

Intervention: Olmesartan 10/20/40 mg/die vs Ramipril 2,5/5/10 mg/die for 12 weeks; 36 weeks more for patient on Olmesartan 40 mg/die

Condition: Elderly with Mild to Moderate hypertension

Study type & design: This is a phase III, multicenter, double blind randomised parallel group study.

Main criteria for inclusion: 1) age >65 and <89, 2) new diagnosis of Grade 1 or Grade 2 essential arterial hypertension (systolic arterial pressure when seated 140-179 mmHg and/or diastolic arterial pressure 90-109 mmHg) or essential arterial hypertension grade 1 or 2 (systolic arterial pressure when seated 140-179 mmHg and/or diastolic arterial pressure 90-109 mmHg) not controlled with current treatment or with intolerance to current treatment.

Main criteria for exclusion

- 1) Grade 3 essential hypertension (systolic blood pressure when seated >180 mmHg and diastolic blood pressure when seated >110 mmHg)
- 2) Secondary or malign arterial hypertension
- 3) Unstable angina
- 4) Cardiac arrhythmia requiring administration of anti-arrhythmic medicines
- 5) Heart failure requiring medical treatment
- 6) Myocardial infarction in the six months prior to enrolment
- 7) Cardiogenic or septic shock
- 8) Haemodynamically significant valvulopathy
- 9) Hereditary/idiopathic angioedema
- 10) History of angioedema associated with previous ACE-inhibitor therapy
- 11) Renal insufficiency
- 12) Hypokaliemia (<3,5 meq/l) or Hyperkalemia (>5 meq/l) confirmed in at least two haematological examinations (if the patient presents baseline hypo or hyperkalemia this value has to be confirmed either by a previous examination or by a new one)
- 13) BMI > 30 kg/m
- 14) Introduction of concurrent therapies among those not permitted and which cannot be suspended without harm to the patient
- 15) History of undesired side effects with ACE-inhibitors or AT1 antagonists