

OLMITIAZ-02

Phase III Study Evaluating the Efficacy and Safety of Olmesartan Medoxomil/Hydrochlorothiazide 40/12.5 mg Combination Therapy Versus Olmesartan Medoxomil 40 mg Monotherapy in Patients With Essential Hypertension

This study has completed the enrolment of patients

SPONSOR: Menarini Ricerche S.p.A.

INTERVENTION: Olmesartan Medoxomil Hydrochlorothiazide 40/12.5 mg vs Olmesartan Medoxomil 40 mg

THERAPEUTIC INDICATION: Essential hypertension

STUDY TYPE & DESIGN: Phase III, randomised, double-blind, multi-centre, multi-national, parallel-group, dose-titration study to be performed in approximately 70 centres in 8 countries (Croatia, Czech Republic, Denmark, Germany, Israel, Italy, Poland, Romania). After conclusion of a 2 weeks single-blind run-in phase, patients will be randomised to the double-blind active treatment period which consists of two phases: First double-blind treatment phase (phase A, from randomisation to week 8): Patients with baseline mean sitting sBP ≥ 160 and ≤ 200 mmHg and dBP ≥ 100 and ≤ 120 mmHg will be randomised in a 1:2 ratio to receive either OM 40 mg or OM/HCTZ 40/12.5 mg to be continued for a total of 8 weeks. After 8 weeks, BP will be assessed and patients reaching the BP goal of $< 140/90$ mmHg or $< 130/80$ mmHg for diabetics will be considered as responders. All patients (responders and non-responders) will then enter the second double-blind treatment phase of the study. Second double-blind treatment phase/ titration phase (phase B, from week 8 to week 16): Responders to phase A treatment will continue to be treated with the same double-blind treatment for an additional 8 weeks of treatment. Non-responders to phase A treatment will be treated as follows: Non-responders to OM 40 mg will be treated with OM/HCTZ 40/12.5 mg for an additional 8 weeks of treatment. Non-responders to OM/HCTZ 40/12.5 mg will be up-titrated to OM/HCTZ 40/25 mg for an additional 8 weeks of treatment.

MAIN CRITERIA FOR INCLUSION: Age ≥ 18 years; Gender: male and female; Patients with a diagnosis of moderate to severe essential hypertension, who are likely to meet the required BP inclusion criteria at randomisation: -Mean sitting dBP ≥ 100 mmHg and ≤ 120 mmHg.

-Mean sitting sBP ≥ 160 mmHg and ≤ 200 mmHg.

MAIN CRITERIA FOR EXCLUSION:

Mean sitting sBP values > 200 mmHg and/or dBP > 120 mmHg.

Pregnant or nursing women.

Patients with secondary hypertension of any aetiology.

Patients with serious disorders which may limit the ability to evaluate the efficacy or safety of the tested Medication;

For further details please refer to www.clinicaltrials.gov