

CLINICAL STUDY REPORT

The Effect of Ezetimibe or pyridoxine in patients with Primary Biliary Cirrhosis

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Protocol Synopsis

PROTOCOL ID: 2006-006742-34

PROTOCOL TITLE: The Effect of Ezetimibe or pyridoxine in patients with Primary Biliary Cirrhosis

PRIMARY ENDPOINT: Change in Cholesterol levels

SECONDARY ENDPOINTS: Change in liver enzymes and haemoglobin levels

STUDY DESIGN: An Open Label, Randomised trial of ezetimibe and pyridoxine, PHASE IV TRIAL.

INCLUSION CRITERIA:

ALL PATIENTS WITH DIAGNOSIS OF PBC AND A CHOLESTEROL LEVEL OF >5MMOL/L.

PATIENTS AGE OVER 16YRS.

MALE AND FEMALE.

ABLE TO GIVE CONSENT

Clinical Study Report:

An early termination report was submitted on March 2013. The study never started, no patients were recruited. This was because of problems identifying research staff, research facilities and site to undertake the study.