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Trial Title: Lifestyle induced weight loss and Liraglutide in the treatment of non-alcoholic steatohepatitis (NASH)

Internal Reference Number / Short title: Lifestyle & Liraglutide in NASH

Ethics Ref: 16/EE/0403

EudraCT Number: 2016-002045-36

RE: Lifestyle induced weight loss and Liraglutide in the treatment of non-alcoholic steatohepatitis (NASH); end of trial - early termination / clinical trial summary results

This clinical trial investigated GLP-1 therapy as a novel intervention for the treatment of non-alcoholic fatty liver disease (NAFLD). It comprised of a head to head comparison of GLP-1 therapy (Liraglutide 1.8mg) compared with diet and lifestyle intervention to determine the weight independent effects of GLP-1 therapy to include clinical, serological & imaging data.

This was a single centre, open label, randomized phase IIa clinical trial. 31 subjects were randomised to either the Liraglutide or lifestyle arms, of which 29 (n=15 Liraglutide, n=14 lifestyle) continued in the study until the primary endpoint (end of intervention) at 12 weeks. 24 subjects (n=12 in both arms) were followed up at 24 weeks to determine any legacy effects of either intervention.

Our results revealed significant improvements in NAFLD and metabolic health including in liver fat, body fat distribution, liver inflammation and lipid handling with both interventions, and significant improvement in glycaemic control in those on Liraglutide when compared to those on lifestyle intervention. Data analysis is ongoing and it is envisaged that data gathered will be published in the academic press within 12 months.

Please do not hesitate to contact us should you require any additional information.

Yours faithfully,

Prof JW Tomlinson