were randomized to either twice daily exenatide (N = 228) or once daily glargine (N = 227) during the 26-week, non-inferiority trial. The Vitality Scale of the Short Form 36, The Diabetes Symptom Checklist—Revised, The EuroQol instrument (EQ-5D), The Treatment Flexibility Scale, and The Diabetes Treatment Satisfaction Questionnaire (DTSQ) were administered at baseline and endpoint. Change from baseline to endpoint was compared within each treatment, and then between treatment groups with analysis of covariance models, controlling for country and baseline scores. RESULTS: At endpoint, exenatide and glargine achieved similar HbA1c reductions. In each patient reported outcome instrument, both treatment groups improved from baseline to endpoint; however no statistically significant differences were observed between the treatment groups. Because exenatide was associated with a higher incidence of nausea, the impact of treatment satisfaction, as measured by the DTSQ, was assessed for those exenatide patients who experienced nausea during the trial (n = 126). These patients demonstrated improvement from baseline to endpoint as well. CONCLUSIONS: Both injectable medications significantly improved the quality of life when added to pre-existing oral therapy. Exenatide, injected twice daily, was associated with an elevated incidence of nausea. However, despite the addition of an injection requirement and side effect of nausea, treatment satisfaction in exenatide group was comparable to that of the glargine group.

**PDB6**

**REDUCTION IN DIABETES DRUGS USE AND DRUG COSTS IN OBESE PEOPLE TREATED WITH ORLISTAT**

Rowe RJ, Cowx MJ, Poole CP, McEwan P, Walker M

1Wythenshawe Hospital, Manchester, UK; 2Cardiff Research Consortium, Cardiff, UK; 3Cardiff University, Cardiff, Wales, UK; 4Roche Products Ltd, Welwyn Garden City, Hertfordshire, UK

**OBJECTIVE:** In addition to weight reduction, there may be other benefits of obesity treatment including improved insulin sensitivity. The purpose of this study was to characterise concomitant diabetes drug use and the related costs in diabetic patients treated with orlistat in the first six months of weight management. METHODS: One hundred overweight diabetic patients were enrolled in a structured weight management clinic and treated with orlistat plus behavioural interventions. Among other measures, weight, glucose control (HbA1c) and drug treatments were recorded. Subjects were followed-up for a maximum of 24 months at intervals of 6 months, with a maximum treatment period of 24 months. RESULTS: The majority of subjects (90%) had type-2 diabetes. They had a median age of 55 years (IQR 47–63) and 55% were women. The mean BMI at baseline was 39.51 with a mean HbA1c of 7.56%. The mean reduction in weight at 6 months was 7.1kg (p < 0.001), with an average absolute HbA1c improvement of 0.62% (p < 0.001). Of the 50 patients treated with insulin at baseline, three no longer required insulin by the 6 month follow up. Of those treated with insulin, the mean insulin dose was 130iu (SD 135.4) at baseline and 90iu (SD 125.4) at 6 months (p < 0.001). Twenty patients (45%) initially treated with oral hypoglycaemic agents alone reduced their dose after 6 months. Despite marked improvement in insulin sensitivity (baseline mean 1.24iu/kg; 6 month mean 0.90iu/kg (p < 0.001)) there was no correlation with BMI change. The average cost of diabetes treatment was £0.82 per day at baseline and £0.59 at 6 months (A 28%; p < 0.001). CONCLUSIONS: Orlistat therapy, in conjunction with a structured weight management programme, appears to reduce the need for concomitant diabetes medication irrespective of weight loss. This reduction is likely to translate into a large cost offset for orlistat treatment.

**PDB7**

**THE METABOLIC EFFECTS OF ORLISTAT AND ROSIGLITAZONE ON INSULIN ACTION IN A GROUP OF CHINESE PATIENTS AFFECTED BY THE METABOLIC SYNDROME**

Loh SC1, Tomlinson B2, Chan JC2, Lee KK2

1The Chinese University of Hong Kong, Shatin, New Territories, Hong Kong; 2The Chinese University of Hong Kong, Hong Kong, China

**OBJECTIVES:** To examine the effects of orlistat and rosiglitazone and assess the changes of cardiovascular risk factors in a group of Chinese patients affected by the metabolic syndrome. METHODS: In a prospective, 6-months randomized single-blinded placebo-controlled study, 58 Chinese participants with type-2 diabetes or impaired glucose tolerance, aged >18 years with a BMI of 23kg/m2 or above were administered orally 120mg orlistat three times daily, rosiglitazone 2mg twice daily or placebo three times daily. Changes in clinical and metabolic parameters of the metabolic syndrome were monitored, including BMI, body fat, glycaemic control, lipid levels and drug tolerability. RESULTS: There were 20 individuals in the rosiglitazone group and 19 individuals in both the orlistat and placebo groups. There were statistically significant differences between the three groups in total cholesterol (p = 0.001), triglycerides (p = 0.037), LDL-cholesterol (p = 0.001), BMI (p = 0.001), hip (p = 0.002) and body fat (p = 0.006). The orlistat group demonstrated improved lipid profiles from baseline, especially on the reduction of total cholesterol (12% p = 0.0005) and LDL (21%, p = 0.0002). This was accompanied by improvements in the fasting insulin levels (p = 0.07) and Homeostatic Model Assessment (HOMA) scores (p = 0.026). In comparison, the rosiglitazone group exhibits maximum improvements in fasting insulin (p = 0.004), 2hr-post OGTT insulin (p = 0.004) and HOMA scores (p = 0.005). Although statistically insignificant, there is a slight increase from baseline in the LDL levels (12%) and body fat (3.7%). CONCLUSIONS: To prevent progression to type-2 diabetes mellitus and its complications, early detection and implementation of appropriate treatment strategies for the metabolic syndrome is crucial. Both rosiglitazone and orlistat appear to be promising in treating the metabolic syndrome.

**PDB8**

**CLINICAL BENEFITS OF PROLONGED-RELEASE NICOTINIC ACID (NIAISPAN®) AND EZETIMIBE IN STATIN-TREATED TYPE-2 DIABETES PATIENTS FAILING TO REACH TARGET CHOLESTEROL LEVELS**

Liens D1, Roze S2, Valentine VJ3, Minshall ME1, Palmer AJ1, Renaudin C1

1Merck Santé, Lyon, France; 2CORE—Center for Outcomes Research, Binningen, Basel, Switzerland; 3CORE—USA, LLC, Fishers, IN, USA

**OBJECTIVES:** To assess the clinical benefits of add-on treatment with Niaspan® (increases HDL-c) or ezetimibe (reduces LDL-c) on coronary heart disease (CHD) in Type-2 diabetes patients failing to reach target cholesterol levels on statin monotherapy. METHODS: Two models were developed to project the clinical benefits of treatment over 10 years. The first model (Monte Carlo simulation) was used to evaluate the impact of simvastatin treatment on lipid levels and identify patients with low HDL-c or high LDL-c. Baseline cohort characteristics were taken from the diabetic sub-population of the 45 study. Patients with LDL-c <3mmol/L and HDL-c <1mmol/L received add-on Niaspan®. Patients with LDL-c >3mmol/L received add-on ezetimibe. Each add-on treatment was compared to statin monotherapy. Treatment effects for both drugs were taken from several clinical trials summarized in the European SPC. The second model (Markov model) was used to evaluate the cumulative incidence of CHD