HAWKE'S BAY CLINICAL RESEARCH COMMITTEE REPORT

CLINICALTRIALS WITHIN THE MEDICAL & PAEDIATRIC SERVICES

AFFINITY - An Australian-lead, Investigator-initiated, Multi-centre, Prospective, Randomised, Parallel group, Double-blind, Placebo-controlled trial to establish the effect(s) of routine administration of fluoxetine (20 mg once daily) in patients with recent stroke.
Principal Investigator: Dr John Gommans

CAMELLIA - A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Effect of Long-term Treatment with BELVIQ (lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk Factors.
Principal Investigator: Dr Robert Leikis

MK0822 – A blinded extension to 5 years for: A Phase 111 Randomised, Placebo-controlled Clinical Trial to assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Menopausal women treated with Vitamin D and Calcium.
Enrolment has closed.
Principal Investigator: Dr Robert Leikis

REDUCE-IT – A multicentre, prospective, randomised, double blind, placebo controlled, parallel group study to evaluate the effect of AMR101 (a fish oil compound) on cardiovascular health and mortality in hypertriglyceridemic patients with cardiovascular disease (or at high risk of CV disease).
Principal Investigator: Dr Richard Luke

REWIND – A phase 111 trial of GLP-1 intervention for Diabetes Evaluation.
This study is designed to assess the effect of Dulaglutide on major cardiovascular events in patients with Type 2 Diabetes.
Enrolment has closed.
Principal Investigator: Dr Miles Williams

SPIRE 1 & SPIRE 2 These are Phase 3 multi-centre, double-blind, randomised, placebo-ontrolled, parallel-group evaluations of the efficacy, safety, and tolerability of BOCOCIZUMAB (PF-04950615), in reducing the occurrence of major cardiovascular events in high risk subjects.
Prinicipal Investigator: Dr M Williams

ALS-8176-503 A randomised, double-blind, placebo-controlled, 2-part study of orally administered ALS-008176 (potent & highly selective inhibitors of both RSV laboratory-adapted A and B strains) to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending dosing and multiple ascending dosing in infants hospitalised with respiratory Syncytial (RSV) infection.
Principal Investigator: Dr Kai Steinmann

hPOD (Hypoglycaemia Prevention in Newborn Babies at Risk of Neonatal Hypoglycaemia). This is a randomised, controlled trial comparing prophylactic oral dextrose gel with placebo in newborn babies.
Principal Investigator: Dr O Grupp