Safety and Effectiveness of Cook MyoSite Incorporated AMDC in

12/LO/0739



NHS Foundation Trust

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
01/1/068	HERA trial: A randomised three arm multi-centre comparison of 1 year and 2 years of Herceptin versus no Herceptin in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy.	4	31/10/2005	Closed - In Follow Up	Υ	Exceeded planned recruitment target.
07/MRE01/68	ALTTO: A randomised, multicentre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer.	19		Closed - In Follow Up	N	Historically less robust feasibility and target setting. Total estimated number of patients given as 19 on the basis of the clinical trial agreement stating 5 patients per year.
09/H1206/97	A Prospective, International, Multi-Centre Study of Clinical Outcomes and Estimated Healthcare Resource Expenditures Associated with the Treatment of Obesity using the LAP-BAND AP Adjustable Gastric banding System.	20		Closed - Follow Up Complete	N	Historically less robust feasibility and target setting. 20- 35 patients was stated as the target recruitment number on the clinical trials agreement.
08/MRE00/42	A post market surveilance Registry of the Biomatrix drug eluting stent.	50	31/03/2011	Closed - Follow Up Complete	Υ	Exceeded planned recruitment target.
11/NIR03/6	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of Tasquinimod in Men with Metastatic Castrate-Resistant Prostate Cancer.	12	31/12/2012	Closed - Follow Up Complete	N	Historically less robust feasibility and target setting.
12/LO/0262	Long-term safety and tolerability of SAR236553 (REGN727) in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study.	4	31/05/2013	Closed - Follow Up Complete	N	Sponsor closed early - study wide recruitment completed. Total estimated number of patients given as 4 on the basis of the clinical trial agreement stating 1 patient per month.
	A Double-blind, Randomized, Placebo-Controlled Study Evaluating the					



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Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
12/EE/0176	Randomised, Phase IV, placebo-controlled, comparative study to evaluate the efficacy and safety of tapering methotrexate (MTX) dosage versus maintaining the dosage in patients with severe active rheumatoid arthritis (RA) who have demonstrated an inadequate response to prior conventional disease-modifying anti-rheumatic drugs (DMARDs) treatment and have initiated RoActemra? (tocilizumab, TCZ) in combination with MTX.		31/03/2015	Closed - Follow Up Complete	Υ	Exceeded planned recruitment target.
13/SC/0311	A randomized, controlled, doubleblind Phase III trial to compare the efficacy, safety and pharmacokinetics of GP2013 plus cyclophosphamide, vincristine, prednisone vs. MabThera? plus cyclophosphamide, vincristine, prednisone, followed by GP2013 or MabThera? maintenance therapy in patients with previously untreated, advanced stage follicular lymphoma.	2	17/08/2018	Closed - Follow Up Complete	N	Rare disease. No patients fitting eligibility criteria were seen.
12/WS/0300	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome.	17	31/03/2016	Open	N/A	Recruitment on track.
13/NW/0463	Risk of Squamous Cell Carcinoma on Skin Areas Treated with Ingenol Mebutate Gel, 0.015% and Imiquimod Cream, 5%.	10	30/11/2015	Open	N/A	Currently recruiting.
09/H0706/22	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of both aliskiren monotherapy and aliskiren/enalapril combination therapy compared to enalapril monotherapy, on morbidity and mortality in patients with chronic heart failure (NYHA Class II - IV). (CSPP100F2301, ATMOSPHERE)	4	03/03/2011	Closed - In Follow Up	Y	Target met.

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Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
12/LO/0062	A Phase 3, Randomized, DoubleBlind, PlaceboControlled Study of the Effects of Ranolazine on Major Adverse Cardiovascular Events in Subjects with a History of Chronic Angina Who Undergo Percutaneous Coronary Intervention with Incomplete Revascularization.	10	30/06/2013	Closed - In Follow Up	Υ	Target met.
14/SC/0033	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	5		Open	N/A	
14/SC/0032	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	5		Open	N/A	
15/LO/0802	The effect of standard versus high energy, low volume oral nutritional supplements in children requiring nutritional support – a pilot trial	3	30/04/2016	Open	N/A	3-7 patients agreed with sponsor.
15/WS/0061	A Randomized, Doubleblind, Eventdriven, Multicenter Study Comparing the Efficacy and Safety of Rivaroxaban with Placebo for Reducing the Risk of Death, Myocardial Infarction or Stroke in Subjects with Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure	5	30/09/2016	Open	N/A	

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