Western Sussex Hospitals



NHS Foundation Trust

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient	Benchmark Met	A - Permissions delayed/ denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
	A multi-centre randomised placebo- controlled trial of prophylactic enteral lactoferrin supplementation to prevent late-onset invasive infection in very preterm infants	22/04/2014													Y	We are a continuing care site for this study and therefore not recruiting patients. The delay between VRA and NHS Permission was the responsibility of the sponsor.	Neither
12/WA/0230	Palliative radiotherapy in addition to self-expanding metal stent for improving outcomes of dysphagia and survival in advanced oesophageal cancer.	03/04/2014	13/02/2015	316	No	Y				Y						Delay caused by need for cross- organisation agreement on IRMER. Organisations providing services were across two regional radiation protection services.Retirement of study research nurse and delay in identifying and recruiting an appropriately trained replacement.	NHS Provider
13/SC/0111	FOCUS4 - Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	30/04/2014							Y						Y	Lack of clinical equipoise regarding availability of treatment arms, as judged by the PI: issue ongoing. NHS permission re-issued 17/06/2015. Site Initiation Visit now delayed due to sponsor availability.	Both
13/NW/0621	The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care (ARCHIE): a double- blind randomised placebo-controlled trial.	12/09/2014									Y					Sponsor requested all sites be research ready in good time for the flu season. Sponsor delay in sending out trial medication - not received until mid February 2015. No potential participants seen between receiving study medication and recruitment window closing at end of March 2015. Next recruitment window opens October 2015.	Sponsor

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13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer	04/06/2014											Y	Y		Delay in NHS Permission was due to requirement for Material Transfer Agreement to send samples to a devolved nation. Site only providing five patients in this rare disease area.Retirement of study research nurse and delay in identifying and recruiting an appropriately trained replacement.	Both
13/LO/1595	COgnitive behavioural therapy vs standardised medical care for adults with Dissociative non-Epileptic Seizures: A multi-centre randomised controlled trial (CODES).	09/09/2014	41968	77	No							Y					Neither
13/NS/0143	Stress Urinary Incontinence; A Pragmatic Multi-centre Non?Inferiority Randomised Controlled Trial: The SIMS Trial	25/09/2014	41967	60	Yes							Y				Site activation by sponsor 13/10/14.	Neither
12/SW/0206	characterisation of solitary pulmonary nodules	07/07/2014	10/10/2014	95	No						Y					No eligible patients identified during screening until first patient recruited 10/10/14.	Neither
12/LO/1109	Prostate Cancer Patients With Spinal Metastasis	31/10/2014	17/06/2015	229	No							Y				Two screen fails. Next eligible patient seen declined to participate on grounds of serious ill health of partner.	NHS Provider
12/WM/0187	A randomised controlled trial of reinforcement of closure of stoma site using a biological mesh	24/10/2014	05/12/2014	42	Yes												

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12/NW/0045	A RandoMised study of best Available therapy versus JAK Inhibition in patients with high risk Polycythaemia Vera or Essential Thrombocythaemia who are resistant or intolerant to HydroxyCarbamide	16/09/2014	28/01/2015	134	No									Y		Rare disease area.	Neither
12/SC/0411	Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)	30/09/2014	42033	121	No					Y						Contract to provide the MSK service was in consultation and staff unable to undertake additional tasks at the time.	NHS Provider
13/LO/1082	Revascularisation or medical therapy in elderly patients with acute anginal syndromes.	09/12/2014									Y					Participants must be over the age of 80 years and so far have been either too unwell to be eligible or so well that randomisation would be inappropriate.	Neither
08/H1102/11 2	Safety and efficacy of intensive versus guideline antiplatelet therapy in high risk patients with recent ischaemic stroke or transient ischaemic attack: a randomised controlled trial	03/02/2015								Y						Study not activated at site by sponsor due to NHS Provider staff jury service and annual leave. Site now activated and frist patient recruited on 10/07/2015.	NHS Provider
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH2	27/02/2015	42116	54	Yes					Y						Study not activated at site by sponsor due to NHS Provider staff jury service and annual leave. Study now active and first patient recruited.	NHS Provider
15/WA/0189	Bedside Inotropy – validation of a non-invasive technique to rapidly measure cardiac contractility	18/05/2015													Y	Very recently approved.	Neither
10/H0802/46	Revascularisation for Ischaemic Ventricular Dysfunction (REVIVED)	12/06/2015													Y	Very recently approved.	Neither
13/SC/0645	Pre-eclampsia in Hospital: Early Induction or Expectant Management	18/03/2015								Y						Staff sickness and annual leave. First patient recruited 01/07/2015.	NHS Provider