

Whittington Hospital NHS Trust Performance in Initiating Q4 19/20

HRA Approval Studies

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	Reasons for Delay	Comments	Reasons for delay correspond to:
17/SC/0434	209815	Biomarker-guided duration of antibiotic treatment in hospitalised patients with suspected sepsis. The ADAPT-Sepsis Trial.	Yes	13/01/2020	64	164	228	28/05/2019	30/05/2019	23/10/2017	24/07/2019	02/08/2019	Please Select...	22/11/2019	A - Permissions delayed/denied	delays caused awaiting green light from the study centre.	Both
18/YH/0358	242342	A randomised controlled trial to establish the clinical and cost effectiveness of expectant management versus preoperative imaging with Magnetic Resonance Cholangiopancreatography (MRCP) in patients with symptomatic gallstones undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones. The Sunflower Study.	Yes	27/08/2019	72	53	125	11/04/2019	24/04/2019	12/12/2018	12/12/2018	05/07/2019	Please Select...	05/07/2019	H - Contracting delays	Delays caused by time taken for Sponsor to agree to costs.	Sponsor
18/LO/2070	246179	A feasibility trial of serial prophylactic exchange blood transfusion (SPEBT) in pregnant women with sickle cell disease (SCD) aiming to improve maternal and infant outcomes TAPS2: Transfusions Antenatally in Pregnant women with SCD	No		19			06/08/2018	24/10/2019	28/03/2019	12/11/2019	12/11/2019	Please Select...	15/11/2019	H - Contracting delays	delays relate to delays with cost & calculations	Neither
19/LO/1215	261663	A Phase 3b, open-label, single-arm, rollover study to evaluate long-term safety in subjects who have participated in other luspatercept (ACE-536) clinical trials	No					31/07/2019	27/12/2019				Please Select...		A - Permissions delayed/denied D - Sponsor Delays	This is a delegated review study. Last correspondence seemed to be an amendment awaiting approval (12/03/2020) before study could go ahead. However, delays in set up further related to COVID 19.	Sponsor
18/NW/0682	249138	Clinical and Cost-effectiveness of Posterior	No		56			21/05/2019	17/07/2019	19/11/2018	15/08/2019	11/09/2019	Please Select...	16/09/2019	C - Closed by sponsor	Whittington study team awaiting	Sponsor

		Cervical Foraminotomy versus Anterior Cervical Discectomy in the Treatment of Cervical Brachialgia: A Multicentre, Phase III, Randomised Controlled Trial (FORVAD Trial)														SIV date since last year. Now suspended due to COVID 19.	
19/SC/0311	262176	ASEPTIC Primary Antibiotic prophylaxis using co-trimoxazole to prevent Spontaneous bacterial Peritonitis in Cirrhosis	No		12			22/07/2019	27/09/2019	07/08/2019	25/09/2019	09/10/2019	Please Select...	12/12/2019	D - Sponsor Delays	This is a delegated review study - delays with sponsor and now recruitment paused due to COVID.	Sponsor
19/HRA/5656	272250	EAGLE: ESCP safe-anastomosis programme in colorectal surgery	No		33			29/11/2019	04/12/2019	18/10/2019	06/01/2020	06/01/2020	Please Select...		J - Other	Cannot recruit due to COVID-19 restrictions.	Neither
18/LO/1818	231542	Intervening with a Manualised Package to Achieve treatment adherence in people with Tuberculosis: the IMPACT study	No		49			11/07/2019	11/12/2019	07/01/2019		29/01/2020	Please Select...		A - Permissions delayed/denied	This is a CRN delegated review study. From the correspondence the central study team were not ready to recruit until April, thus delays. Shortly after this, put on hold due to COVID 19.	Sponsor
19/NI/0024	255486	Efficacy and Safety Study of PRN1008 in Patients with Pemphigus	No					18/11/2019	14/02/2020	15/04/2019			Please Select...		J - Other	setup on hold due to COVID 19.	Neither
20/NE/0014	272055	KD-CAAP (Multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIg) and aspirin, versus IVIg and aspirin for prevention of coronary artery aneurysms (CAA) in Kawasaki disease (KD))	No					10/02/2020	28/02/2020	16/01/2020			Please Select...		J - Other	setup on on hold due to COVID 19.	Neither
20/EE/0101	281712	RECOVERY trial (urgent public health research study)	Yes	02/04/2020	9	6	15	16/03/2020	18/03/2020	17/03/2020	27/03/2020	27/03/2020	Please Select...	27/03/2020			Please Select...
19/LO/1566	267041	A Randomized, Placebo-controlled, Phase 2 Study to Evaluate the Safety and Pharmacodynamics of Once-daily Oral IW-1701 in Patients with Stable Sickle Cell Disease. Strong SCD	No		71			05/09/2019	21/11/2019	21/11/2019	22/01/2020	31/01/2020	Please Select...	25/02/2020	J - Other	Recruitment stopped due to COVID 19.	Neither

Whittington Hospital NHS Trust Performance in Delivery Q4 19/20

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial	Comments
18/LO/0079	232937	LJPC-401 for iron overload in adults with TDT	Number Agreed	3	3	Date Agreed	25/11/2019	5	25/11/2019	5	Withdrawn By Sponsor	