NHS
Western Sussex Hospitals
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| Research Ethics Committee Reference Number | Integrated Research Application System (IRAS) number | Name of Trial | Date Site Invited | Date Site Selected | HRA Approval Date | Date Site Confirmed By Sponsor | Date Site Confirmed | Date Site Ready to Start | Date of First Patient Recruited | Non-Confirmation Status | Duration between Date site selected and First Patient (days) | 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: |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16/WS/0068 | 199202 | Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour - QUIDS | 19/05/2016 | 03/10/2016 | 13/07/2016 | 27/06/2016 | 10/08/2016 | 31/10/2016 | 02/11/2016 | | 30 | Yes | | | | | | | | | | | SIV delayed by sponsor. Final protocol presented by sponsor at SIV (03/10/2016) which necessitated additional communication to resolve agreement to continue. | |
| 16/LO/1822 | 212944 | A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA) | 11/05/2017 | 05/10/2016 | 07/12/2016 | | | | | Site declined to participate | | Site Not Confirmed | | | | | | | | | | | Site declined 06/01/2017 - PI no longer able to act as PI. No other consultant able to take on the role of PI for the duration of the study. | |
| 17/EM/0075 | 222172 | Evaluating the tolerance, compliance and acceptability of a nutritionally complete, high energy, high protein, enteral feed in adults ? a pilot study | 01/02/2017 | 27/03/2017 | 27/03/2017 | 24/04/2017 | 02/05/2017 | 08/05/2017 | 17/05/2017 | | 51 | Yes | | | | | | | | Y | | | Final complete costing template not received until 24/04/2017 from sponsor. | Both |
| 16/HRA/5525 | 210175 | MindSHINE 3: A definitive randomised controlled trial investigating two online wellbeing interventions to reduce NHS staff stress | 17/01/2017 | 06/04/2017 | 23/01/2017 | 06/04/2017 | 08/05/2017 | 15/05/2017 | 06/06/2017 | | 61 | Yes | | | | | | | | | | | | |
| 16/WM/0036 | 180476 | Accuracy of a rapid intrapartum test for maternal group B streptococcal colonisation and its potential to reduce antibiotic usage in mothers with risk factors. | 28/12/2016 | 12/05/2017 | 23/08/2016 | 23/06/2017 | 05/07/2017 | | | | | Within 70 Days | | | | Y | | | | | | | Sub-category - delay intrinsic in study design<br>Nature of delay - modifications to clinical testing guidelines | Sponsor |
| 17/YH/0071 | 223653 | A MULTICENTER OPEN- | | | | | | | | | | | | | | | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16/NW/0517 | 188554 | A phase III study to determine the role of ixazomib as an Augmented Conditioning therapy in salvage autologous stem cell transplant (ASCT) and as a post-ASCT Consolidation and maintenance strategy in patients with Relapsed multiple myeloma. | 29/09/2016 | 05/04/2017 | 27/10/2016 | | | | | | | No | | | | | Y | | | | | | Delay due to time taken for study review and consultation by local clinicians. Local information pack of documents was provided to site prior to site having a confirmed PI. | NHS Provider |
| 15/NS/0113 | 188563 | The clinical and cost effectiveness of surgical interventions for stones in the lower kidney: The PUrE RCT- Percutaneous Nephrolithotomy (PNL), Flexible Ureterorenoscopy (FURS) and Extracorporeal Lithotripsy (ESWL) for lower pole Kidney stones. | 04/05/2017 | 04/05/2017 | 09/06/2017 | 07/06/2017 | 14/06/2017 | | | | | Within 70 Days | Y | | | | | | | | | | Delays due to non-England lead review of study amendment to add WSHT as a site; amendment for WSHT as a site submitted 12/06/17 by sponsor, passed on by NRS to HRA on 04/07/17 and HRA confirmation (no HRA assessment required - non-substantial amendment) received 12/07/17. Advice received from NRS permissions stated "cannot open the study at the site until HRA Approval for the amendment is in place". | Neither |
| 17/SC/0142 | 215503 | Evaluating the clinical and cost-effectiveness of permissive hypotension in critically ill patients aged 65 years or over with vasodilatory hypotension | 03/03/2017 | 11/05/2017 | 24/04/2017 | | | | | | | Within 70 Days | | | | | | | | | | | | |