Streamline C Protocol Summary

1.1. Summary of Trial Design

Title:	Streamlining Staging of Colorectal Cancer with Whole Body MRI
Short Title/acronym:	Streamline C
Sponsor name & reference:	UCL/11/0097
Funder name & reference:	HTA
ISRCTN no:	*Pending*
Design:	Multicentre comparison
Overall aim:	To evaluate whether early whole body magnetic resonance Imaging (WB-MRI) increases per patient sensitivity for metastasis in colorectal cancer compared to standard NICE-approved diagnostic pathways.
Primary endpoint:	Per patient sensitivity for metastasis detection by whole body MRI (WB-MRI) compared to standard staging pathways in newly diagnosed colorectal cancer
Secondary endpoints:	1. The time and test number taken to reach, and the nature of, the first major treatment decision based on WB-MRI in comparison to standard staging pathways. 2. Diagnostic accuracy of WB-MRI and conventional staging pathways for local tumour staging and detection of metastasis in comparison to an expert derived consensus reference standard. 3. Lifetime incremental cost and cost-effectiveness of staging using WB-MRI compared to standard diagnostic pathways. 4. Patient experience of staging using WB-MRI in comparison to standard diagnostic pathways and priorities placed by patients on differing attributes related to competing staging pathways. 5. Inter-observer variability in WB-MRI analysis and affect of diagnostic confidence on staging accuracy. 6. Diagnostic accuracy of limited T1 and diffusion weighted sequences compared to full multi-sequence WB-MRI protocols.
Target accrual:	322
Inclusion & exclusion criteria:	**Inclusion criteria:** • Adult patients (18 or over) with histologically proven or suspected colorectal cancer referred

	for staging. • Suspicion of colorectal cancer defined as: Presence of a mass highly suspicious for colorectal cancer on endoscopy, barium enema, CT colonography or other imaging which triggers staging investigations. • Patient must have given written informed consent and be willing to comply with the protocol intervention and follow up. **Exclusion criteria:** • Any psychiatric or other disorder likely to impact on informed consent • Evidence of severe or uncontrolled systemic disease which make it undesirable for the patient to participate in the trial • Pregnancy • Contraindications to MRI (e.g. cardiac pacemaker, severe claustrophobia, inability to lie flat) • Polyp cancer (because metastatic disease in these patients is vanishingly rare)
Planned number of sites:	9 (including 5 Imaging hubs)
Target Country	UK
Trial Procedure:	All patients will undergo a whole body MRI protocol in addition to the standard staging protocol employed at their institution.
Anticipated duration of recruitment:	3 years
Duration of patient follow up:	12 months
Definition of end of trial:	12 months after enrolment of the final patient.
Other related research:	Sub-study of WB-MRI generalisability

1.2. Trial Schema