The University of Nottingham

ISRCTN 63231313

RECAST 3

REMOTE ISCHAEMIC CONDITIONING AFTER STROKE TRIAL 3

INVESTIGATOR SITE FILE INDEX

	Contacts/ Investigator Site Personnel Contact details of trial staff **Section A: Pre-trial opening**
A.1	**Trial development Documentation** • Minutes of initial meeting with Sponsor • Sponsor confirmation of support • Site selection • Vendor selection • Risk Assessment • Peer view selection • Funding application • Contracts with funder and vendor
A.2	**Study protocol and associated documents – final versions** • Current protocol signed and dated by the CI • Information Sheets, Consent Forms, Investigator brochure • Case Report Forms, Other data collection documents
A.3	**Approval and Agreements** • National ethical and competent authority approval • EudraCT email • Local site specific assessment - where applicable • Local NHS Trust R&D approval, capability and capacity • Sponsor/Chief Investigator agreement • Sponsor/participating site non-commercial agreement • Statement of activities/Schedule of Events • Insurance letter (including superseded letters)
A.4	**Staff Participation** • Site Responsibility (Delegation) Log, RF2 TA008 • CV and training records (GCP) • Attendance at Investigator Training, RF1 TA008 • Evidence of Site Initiation • Regulatory green light e-mail from the sponsor • SOP Compliance Form RF3 TA008
A.5	**Medical Testing and Pharmacy (where applicable)** • Accreditation/certification of supporting laboratories and pharmacies • 'Normal ranges' issued by local laboratories • Investigational product handling (where applicable) – local procedures where not in the study protocol • Investigational product control (where applicable) – local procedures where not in the study protocol • Investigational medicinal product records – certificate of analyses, shipping records, labelling to be used • QP Certification •

A.6	**Randomisation and Blinding** • Randomisation, blinding and un-blinding procedures where not in the study protocol
A.7	**Database Build** • Database specification documentation • User acceptance testing • Validation documentation • Security and access arrangements • Disaster recovery plan
	Section B: Ongoing Trial
B.1	**Study protocol amendments and approvals** • Log of study documentation amendments RF1 TA013 • Current versions of trial documents, fully signed protocol • Previous versions of trial documents when superseded, clearly marked as such • Sponsor confirmation of amendment categorisation • Ethics committee, HRA and competent authority approvals of amendments
B.2	**Staff Participation (ongoing trial)** • Updated RF1 TA008 (Site delegation log) to include new trial staff • Updated CVs and training records (GCP) • Updated attendance at investigator training, RF1 TA008
B.3	**Informed Consent** • Signed consent forms of all trial participants • Participant Screening and Enrolment Log, RF1 TA011
B.4	**Medical Testing and Pharmacy (updates where applicable)** • Updated accreditation/certification of supporting laboratories and pharmacies • Updated 'normal ranges' issued by local laboratories • Documented evidence of any changes and their implementation to investigational product handling (where applicable) – local procedures where not in the study protocol • Documented evidence of any changes and their implementation to • investigational product control (where applicable) – local procedures where not in the study protocol • Updated investigational medicinal product records – certificate of analyses, shipping records, amended labelling to be used (if any)
B.5	**CRFs and Source Documents** • Completed CRF's and amended CRFs • Source documents related to the trial • Ongoing database amendments, alterations and revision documentation and evidence • Data management plan, database lock plan and procedures • Monitoring plan

B.6	**Serious Adverse Events and Serious GCP Breaches** • SAE reporting forms RF1 TA014 • eSUSAR / CIOMs form (IMP trials only) • SAE reporting forms to the ethics committee • Annual safety reports and Development Safety Update Reports (DSUR) to eithics committee and regulatory authority (where applicable) • Evidence of notification of actions to be taken and their implementation following a SUSAR (where applicable) • GCP breach report, correspondence with the MHRA and REC and subsequent corrective action documentation and evidence
B.7	**Biological Materials (if relevant to the study)** • List and location of retained samples • Transfer agreements to other institutions
B.8	**Audit and Reporting** • Annual progress report(s) to host institution, the ethics committee and competent authority (where applicable) • Monitoring reports • Sponsor audit reports and corrective action forms • Data Monitoring Committee reports (as appliciable) • Trial Steering Committee reports (as applicable) • Statistical analyses reports • Funder reports
B.9	**Vendor Management** • Correspondence with and evidence of vendor performance oversight • Contracts for new vendors and correspondence with and evidence of performance management and oversight
B.9	**Miscellaneous** • Correspondence - letters, relevant emails
C.1	**Section C: Trial Completion** **Closure** • Notification of study closure to the ethics committee • Notification of study closure to the competent authority (where applicable): CESP emails • Notification of study closure to the host organisation • Notification of study closure to the sponsor • Treatment allocation and decoding documentation • Documentation of IMP return and/or destruction and pharmacy records
C.2	**Audit** • Final study report to REC and funder • Evidence of upload of trial resuts to EudraCT • Final close out audit report (as applicable) • Publication
C.3	**IMP Management** • IMP and placebo accountability logs • Evidence of destruction of surplus stock

- This file must be kept for 7 years from the date of issue of the final study report

- It is acceptable for any superseded documents to be kept in a separate archive file with appropriate file note explaining location