

STOP-ACEi Amendment Log

Study title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease; The STOP-ACEi Trial

EudraCT number: 2013-003798-82

REC reference: 13/YH/0394

Chief Investigator: Prof Sunil Bhandari



REC approved study document versions

Document	Current approved version	Previous approved versions
Protocol	v4.0, 25-Apr-2019	v3.0, 14 May 2014, v2.1, 24 Jan 2014
Participant Information Sheet (PIS)	v3.0, 10 Dec 2014	v2.2, 28 Jan 2014
GDPR addendum to PIS	v1.0, 03-Dec-2018	-
Text for STOP-ACEi participant thank you letter	V1.0, 25-Apr-2019	-
Informed Consent Form (ICF)	v3.1, 24 Mar 2015	v3.0, 14 May 2014; v2.2, 05 Feb 2014; v2.1, 24 Jan 2014
GP letter – treatment continuation	v2.0, 06 Jan 2014	-
GP letter – treatment discontinuation	v2.0, 06 Jan 2014	-
Letter to accompany PIS	v2.0, 10 Dec 2014	v1.0, 01 Nov 2013
Clinic poster	v2.0, 06 Jan 2014	-
Advertising text	v1.0, 01 Nov 2013	-
Participant advice letter – treatment continuation	v1.0, 01 Nov 2013	-
Participant advice letter – treatment discontinuation	v1.0, 01 Nov 2013	-
Participant diary	No longer in use	v1.0, 01 Nov 2013
KDQOL-SF™	v1.3	-
MRC START in STOP-ACEi Sub-study Protocol	v1.0, 10 Dec 2014	-

Amendments

SA = substantial amendment, NSA = non-substantial amendment

Nb. Amendments that comprise addition of new sites, new site investigators or a change to an existing site investigator only are always considered 'substantial' and do not require additional Sponsor assessment of substantiality.

SA/ NSA	No.	Date of Sponsor substantiality assessment	Date submitted	Changes	New document versions	Date of Approval	
						REC	MHRA
NSA	-	-	05-Feb-2014	ICF - Error correction. Incorrect PIS version stated on ICF.	ICF, v2.2, 05 Feb 2014	07-Feb-2014	-
SA	01	15-May-2014	16-May-2014	Protocol – Minor clarifications and changes to wording, including eligibility criteria, primary outcome, minimisation variables, trial treatment and sample analysis. ICF – Marked as confidential and fax number added. PI changes – Bradford Royal, Lister (Stevenage), Queen Alexandra (Portsmouth), Royal Sussex, Salford Royal, St James' (Leeds), Sunderland Royal, Western Infirmary (Glasgow). New sites – University Hospital Coventry, Royal Cornwall Hospital.	Protocol, v3.0, 14 May 2014 ICF, v3.0, 14 May 2014	30-May-2014	-
SA	02	-	22-Sep-2014	PI changes – Gloucestershire Royal Hospital, King's College Hospital. New sites – New Cross Hospital (Wolverhampton), Birmingham City Hospital, Hammersmith Hospital (Imperial, London), Royal Shrewsbury Hospital, Northwick Park Hospital (NW London).	nil	25-Sep-2014	-
SA	03	-	09-Dec-2014	PI changes – The York Hospital. New sites – Colchester General Hospital.	nil	11-Dec-2014	-

SA/ NSA	No.	Date of Sponsor substantiality assessment	Date submitted	Changes	New document versions	Date of Approval	
						REC	MHRA
SA	04	11-Feb-2015	12-Feb-2015	Implemented on 17 Aug 2015 due to delays with MMI website development. New sub-study (MRC START) – Addition of MRC START sub-study documents. Letter to Accompany PIS – Addition of link to MMI resource if randomised to receive MMI. No changes to content. PIS – Addition of link to MMI resource if randomised to receive MMI. No changes to content.	MRC START in STOP-ACEi MMI Protocol, v1.0, 10 Dec 2014 Letter to accompany PIS, v2.0, 10 Dec 2014 (standard and MMI versions) PIS, v3.0, 10 Dec 2014 (standard and MMI versions)	09-Mar-2015	-
NSA	-	16-Mar-2015	24-Mar-2015	ICF - Error correction. Incorrect PIS version stated on ICF. Released alongside SA04.	ICF, v3.1, 24 Mar 2015	28-Apr-2015	-
SA	05	-	22-Jul-2015	New sites – South Tees, Southend, Calderdale and Huddersfield, Barts Health, NHS Fife.	nil	22-Jul-2015	-
SA	06	-	10-Feb-2016	New sites – Central Manchester University Hospitals, Nottingham University Hospitals, Dorset County Hospital PI change – Royal Free	nil	10-Feb-2016	-
SA	07	-	07-Apr-2016	PI change – Royal Sussex	nil	11-Apr-2016	-
SA	08	-	19-Oct-2016	New sites – Southern HSCT, Northern HSCT, NHS Tayside, Peterborough and Stamford Hospitals PI changes –Royal Free, Newcastle Upon Tyne	nil	31-Oct-2016	-
SA	09	-	22-Mar-2017	New sites – Western HSCT, Betsi Cadwaladr UHB, Barking Havering Redbridge. PI changes – Heartlands, Lister, Northern HSCT.	nil	29-Mar-2017	-
SA	10	-	22-Aug-2017	New site – Epsom and St Helier.	nil	31-Aug-2017	-

SA/ NSA	No.	Date of Sponsor substantiality assessment	Date submitted	Changes	New document versions	Date of Approval	
						REC	MHRA
SA	11	-	15-Jan-2018	PI change – Royal Sussex	nil	18-Jan-2018	-
NSA	-	n/a	06-Dec-2018 (date disseminated)	Addition of GDPR addendum to PIS. No review by REC or R&D departments required, in line with HRA advice.	GDPR addendum, v1.0, 03-Dec-2018	-	-
SA	12	06-Nov-2018	21-Jun-2019	Protocol – Changes to study timeframes, expansion of visit window, changes to pharmacovigilance section including the RSI, risk-adapted reporting timeframes for SAEs, removal of participant diaries, Sponsor name change, other minor changes and corrections. Text for thank you card or letter – new document introduced.	Protocol v4.0, 25-Apr-2019 Text for thank you card or letter v1.0, 25-Apr-2019	REC: 23-Aug-2019 HRA: 19-Sep-2019	09-Jul-2019
SA	13	-	28-Apr-2020	PI changes – Lister, Glan Clywd, Huddersfield. Site name changes/mergers – Colchester (East Suffolk and North Essex NHSFT), University Hospitals Birmingham NHS FT and Heart of England NHS FT (merging under University Hospitals Birmingham NHS FT), Manchester (Manchester University NHS FT), Hull (Hull University Teaching Hospitals NHS Trust), Swansea (Swansea Bay University Health Board)	nil	30-Apr-2020	

All CRFs for STOP-ACEi are based on v3.0 of the Protocol. No changes were required to the follow-up CRFs with the introduction of Protocol v4.0. The SAE form (v2.0) is based on v4.0 of the Protocol.