Trial Management & Data Management

Investigator Meeting

1st May 2015, University of Birmingham Medical School

BIRMINGHAM CLINICAL TRIALS UNIT

UNIVERSITY OF BIRMINGHAM

Hull and East Yorkshire Hospitals NHS Trust

NHS

Common problems with ICFs

ICF not on headed paper

Trial ID not completed

Boxes ticked instead of initialled

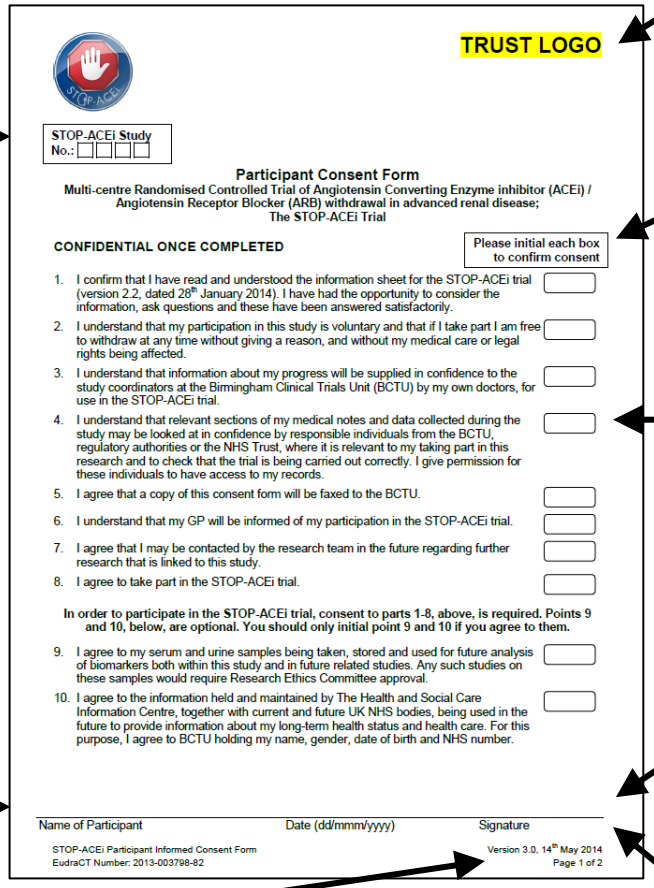
Some required boxes not initialled

Missing signatures / dates

Clinician counter-signing ICF not on del. log.

Incorrect version no.

Clinician counter-signing ICF on different date



TRUST LOGO

STOP-ACEi Study No.: ☐☐☐☐

Participant Consent Form

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

CONFIDENTIAL ONCE COMPLETED

Please initial each box to confirm consent

1. I confirm that I have read and understood the information sheet for the STOP-ACEi trial (version 2.2, dated 28th January 2014). I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily. ☐
2. I understand that my participation in this study is voluntary and that if I take part I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected. ☐
3. I understand that information about my progress will be supplied in confidence to the study coordinators at the Birmingham Clinical Trials Unit (BCTU) by my own doctors, for use in the STOP-ACEi trial. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at in confidence by responsible individuals from the BCTU, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research and to check that the trial is being carried out correctly. I give permission for these individuals to have access to my records. ☐
5. I agree that a copy of this consent form will be faxed to the BCTU. ☐
6. I understand that my GP will be informed of my participation in the STOP-ACEi trial. ☐
7. I agree that I may be contacted by the research team in the future regarding further research that is linked to this study. ☐
8. I agree to take part in the STOP-ACEi trial. ☐

In order to participate in the STOP-ACEi trial, consent to parts 1-8, above, is required. Points 9 and 10, below, are optional. You should only initial point 9 and 10 if you agree to them.

9. I agree to my serum and urine samples being taken, stored and used for future analysis of biomarkers both within this study and in future related studies. Any such studies on these samples would require Research Ethics Committee approval. ☐
10. I agree to the information held and maintained by The Health and Social Care Information Centre, together with current and future UK NHS bodies, being used in the future to provide information about my long-term health status and health care. For this purpose, I agree to BCTU holding my name, gender, date of birth and NHS number. ☐

Name of Participant | Date (dd/mmm/yyyy) | Signature

STOP-ACEi Participant Informed Consent Form
EudraCT Number: 2013-003798-82

Version 3.0, 14th May 2014
Page 1 of 2

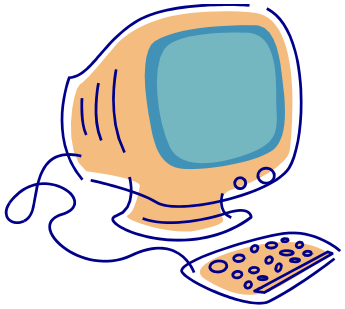
CRFs and data entry

- CRFs are in your site file or can be downloaded from the trial website
  - CRF01 – Randomisation Form
  - CRF02 – Baseline assessment
  - CRF03 – Telephone follow-up
  - CRF04 – 3-monthly visits
  - CRF05 – Additional clinical visits
  - CRF06 – Lab results – used by central lab staff
  - CRF10 – SAE form
- Participant diaries are there to help fill in the AE and clinic visit parts of the CRFs
- Don’t forget KDQOL-SF questionnaires

CRFs and data entry

- Completed paper CRFs can be submitted to BCTU by post, fax or email

- Can enter data directly into online system – will check for errors / omissions



- Please keep originals of CRFs at site.
- Please contact BCTU if you have queries

Login

- You will need:
  - A Unique Username – BCTU will provide after SIV
  - A Unique Password – you will set

- No access until site fully approved

- Once you have your Username and you can set your password at: https://www.trials.bham.ac.uk/password/

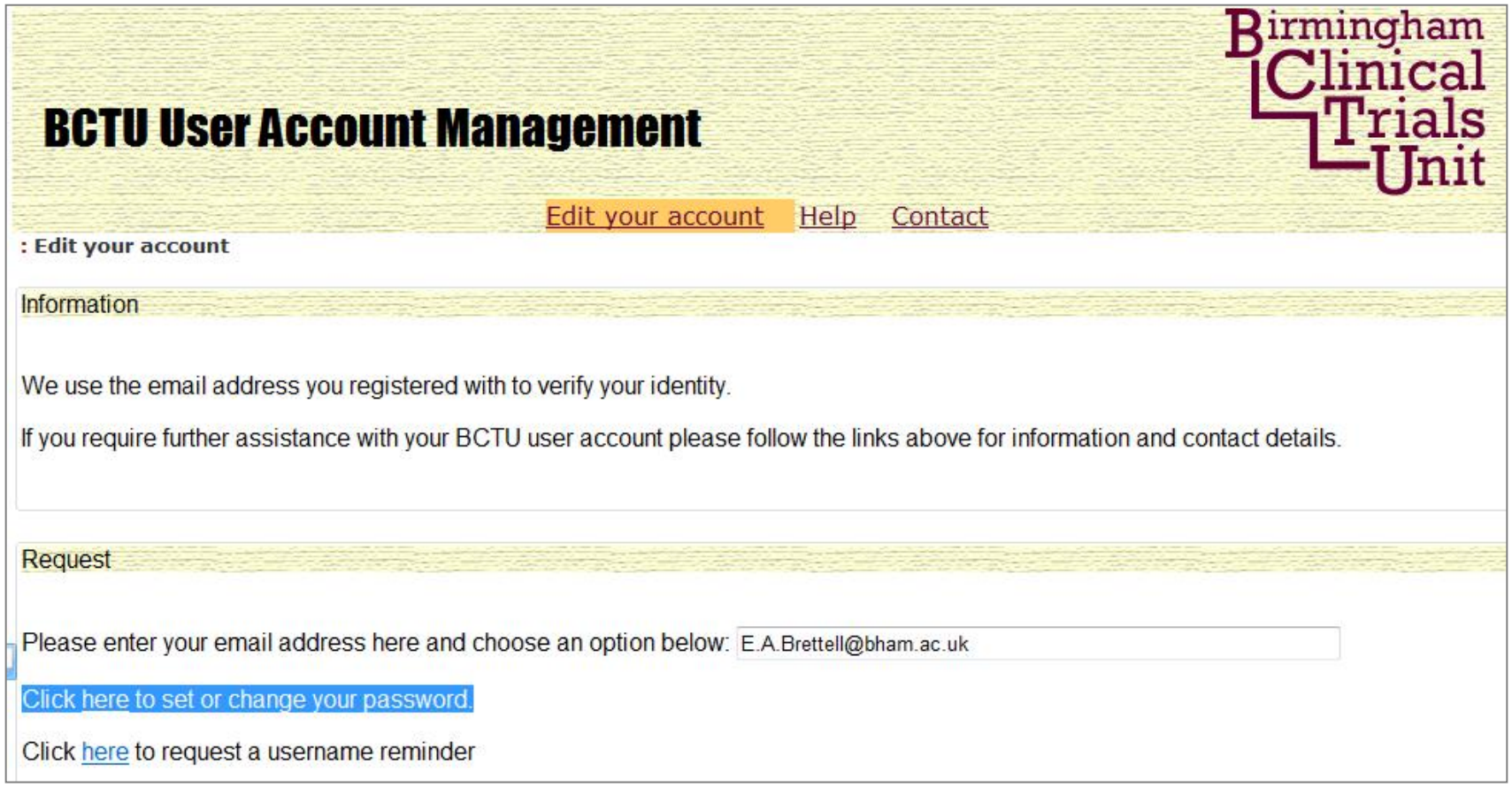
- Activate your password by following instructions in e-mail.

- Check your 'Junk Email' folder
  - Can manually add bctu-webadmin@contacts.bham.ac.uk to your list of safe senders in your email clients

- Can then access the STOP-ACEi Online System at: https://www.trials.bham.ac.uk/STOPACEi

Login

- https://www.trials.bham.ac.uk/password/



Entering a patient

DEMO – entering and randomising a patient to STOP-ACEi

Online forms

DEMO – Creating and completing a form online

CRF return rates

Time-point	Form	Total Forms Due	Forms Not Expected	Returned		
				No.	% of due	% of expected
Baseline	Consent	48	-	48	100.0	100.0
	Baseline	48	-	46	95.8	95.8
	KDQOL-SF™	48	1	45	93.8	95.7
4-6 week	Phone FU	41	1	35	85.4	87.5
3 month	Follow-up	19	0	14	73.7	73.7
6 month	Follow-up	5	0	5	100.0	100.0
9 month	Follow-up	1	0	0	0.0	0.0
12 month	Follow-up	-	-	-	-	-
	KDQOL-SF™	-	-	-	-	-
15 month	Follow-up	-	-	-	-	-
18 month	Follow-up	-	-	-	-	-
21 month	Follow-up	-	-	-	-	-
24 month	Follow-up	-	-	-	-	-
	KDQOL-SF™	-	-	-	-	-
27 month	Follow-up	-	-	-	-	-
30 month	Follow-up	-	-	-	-	-
33 month	Follow-up	-	-	-	-	-
36 month	Follow-up	-	-	-	-	-
	KDQOL-SF™	-	-	-	-	-
Total for all forms		210	2	193	91.9	92.8

Common issues with form completion

Gastrointestinal	No ☑ Yes ☐ – if yes, please provide details:			
Please only record GI symptoms that the responsible clinician considers significant				
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Bloating, abdominal distention or abdominal pain	☐	☐	...../...../.....	.....
Constipation	☐	☐	...../...../.....	.....
Dyspepsia	☐	☐	...../...../.....	.....
Gastritis	☐	☐	...../...../.....	.....
Loose stools / diarrhoea	☐	☐	...../...../.....	.....
Nausea / vomiting	☐	☐	...../...../.....	.....
Ulceration	☐	☐	...../...../.....	.....
Other GI condition	☐	☐	...../...../.....	.....

Box ticked 'No'

Rest of this section can be left blank

Common issues with form completion

Gastrointestinal	No ☐ Yes ☑ – if yes, please provide details:			
Please only record GI symptoms that the responsible clinician considers significant				
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Bloating, abdominal distention or abdominal pain	☑	☐	../../..	
Constipation	☑	☐	../../..	
Dyspepsia	☑	☐	../../..	
Gastritis	☐	☑	30/JUN/2013	
Loose stools / diarrhoea	☑	☐	../../..	
Nausea / vomiting	☑	☐	../../..	
Ulceration	☑	☐	../../..	
Other GI condition	☑	☐	../../..	

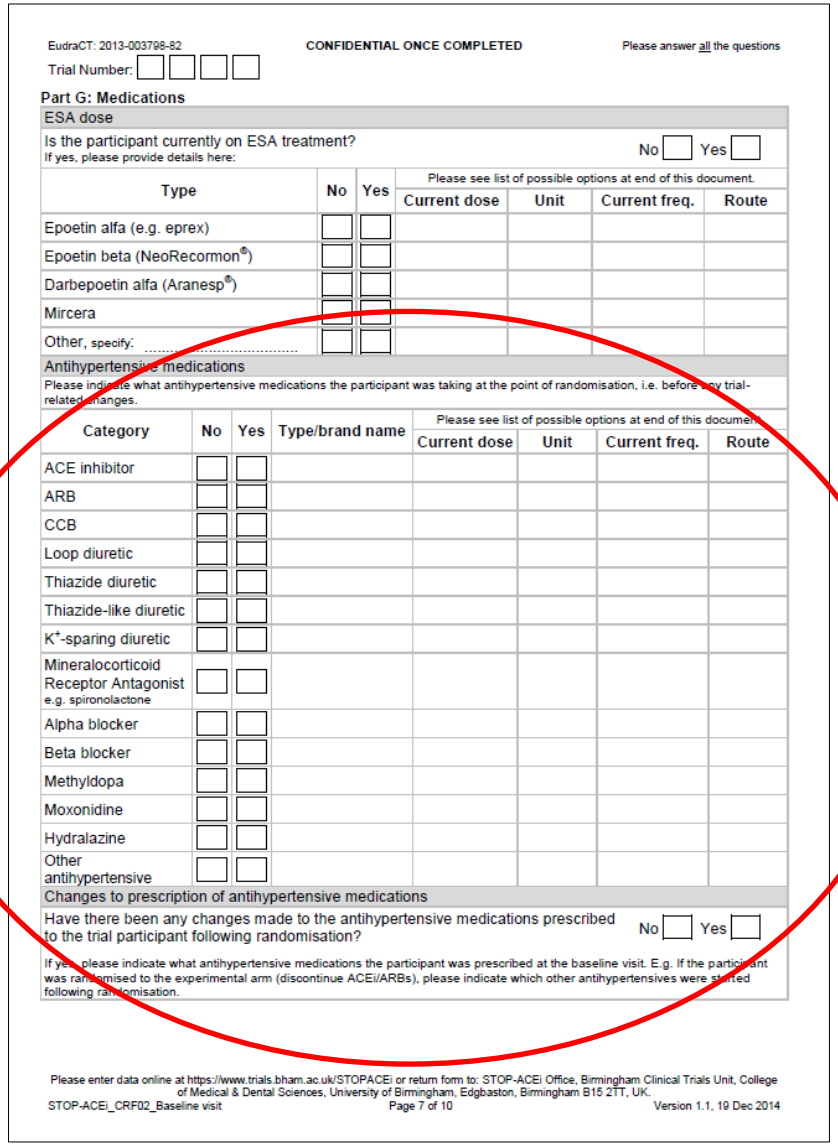
Box ticked 'Yes'

Please fill in a date and record any further information under Details

Ensure that all the other boxes are ticked 'No'

Common issues with form completion

Baseline Visit (CRF02)



EudraCT: 2013-003798-82 **CONFIDENTIAL ONCE COMPLETED** Please answer all the questions

Trial Number: ☐☐☐☐

Part G: Medications

ESA dose

Is the participant currently on ESA treatment? No ☐ Yes ☐

If yes, please provide details here:

Type	No	Yes	Please see list of possible options at end of this document. Current dose	Unit	Current freq.	Route
Epoetin alfa (e.g. eprex)	☐	☐				
Epoetin beta (NeoRecormon®)	☐	☐				
Darbepoetin alfa (Aranesp®)	☐	☐				
Mircera	☐	☐				
Other, specify:	☐	☐				

Antihypertensive medications

Please indicate what antihypertensive medications the participant was taking at the point of randomisation, i.e. before any trial-related changes.

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document. Current dose	Unit	Current freq.	Route
ACE inhibitor	☐	☐					
ARB	☐	☐					
CCB	☐	☐					
Loop diuretic	☐	☐					
Thiazide diuretic	☐	☐					
Thiazide-like diuretic	☐	☐					
K^+-sparing diuretic	☐	☐					
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☐	☐					
Alpha blocker	☐	☐					
Beta blocker	☐	☐					
Methyldopa	☐	☐					
Moxonidine	☐	☐					
Hydralazine	☐	☐					
Other antihypertensive	☐	☐					

Changes to prescription of antihypertensive medications

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation? No ☐ Yes ☐

If yes, please indicate what antihypertensive medications the participant was prescribed at the baseline visit. E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARBs), please indicate which other antihypertensives were started following randomisation.

Please enter data online at https://www.trials.bham.ac.uk/STOPACEi or return form to: STOP-ACEi Office, Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK.

STOP-ACEi_CRF02_Baseline visit Page 7 of 10 Version 1.1, 19 Dec 2014

Common issues with form completion

Antihypertensive medications

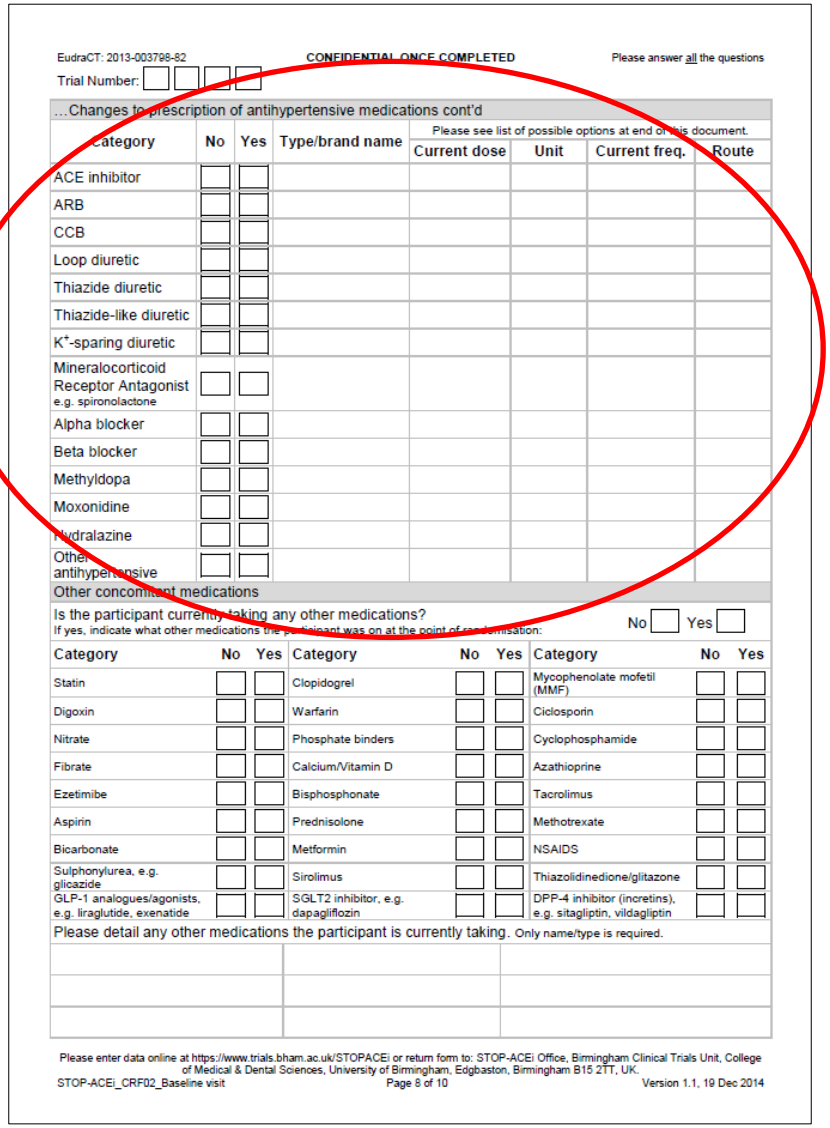
Please indicate what antihypertensive medications the participant was taking at the point of randomisation, i.e. before any trial-related changes.

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document. Current dose	Unit	Current freq.	Route
ACE inhibitor	☑	☐					
ARB	☐	☑	LOSARTAN	10	mg	OD	O
CCB	☐	☑	AMLODIPINE	5	mg	OD	O
Loop diuretic	☑	☐					
Thiazide diuretic	☑	☐					
Thiazide-like diuretic	☑	☐					
K^+-sparing diuretic	☑	☐					
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☑	☐					
Alpha blocker	☑	☐					
Beta blocker	☐	☑	BISOPROLOL	5	mg	OD	O
Methyldopa	☑	☐					
Moxonidine	☑	☐					
Hydralazine	☑	☐					
Other antihypertensive	☑	☐					

ARB included

Common issues with form completion

Baseline Visit (CRF02)



EudraCT: 2013-003798-82 CONFIDENTIAL ONCE COMPLETED Please answer all the questions

Trial Number:

…Changes to prescription of antihypertensive medications cont'd

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document. Current dose	Unit	Current freq.	Route
ACE inhibitor							
ARB							
CCB							
Loop diuretic							
Thiazide diuretic							
Thiazide-like diuretic							
K^+-sparing diuretic							
Mineralocorticoid Receptor Antagonist e.g. spironolactone							
Alpha blocker							
Beta blocker							
Methyldopa							
Moxonidine							
Hydralazine							
Other antihypertensive							

Other concomitant medications

Is the participant currently taking any other medications? No Yes

If yes, indicate what other medications the participant was on at the point of randomisation:

Category	No	Yes	Category	No	Yes	Category	No	Yes
Statin			Clopidogrel			Mycophenolate mofetil (MMF)		
Digoxin			Warfarin			Ciclosporin		
Nitrate			Phosphate binders			Cyclophosphamide		
Fibrate			Calcium/Vitamin D			Azathioprine		
Ezetimibe			Bisphosphonate			Tacrolimus		
Aspirin			Prednisolone			Methotrexate		
Bicarbonate			Metformin			NSAIDS		
Sulphonylurea, e.g. glicazide			Sirolimus			Thiazolidinedione/glitazone		
GLP-1 analogues/agonists, e.g. liraglutide, exenatide			SGLT2 inhibitor, e.g. dapagliflozin			DPP-4 inhibitor (incretins), e.g. sitagliptin, vildagliptin		

Please detail any other medications the participant is currently taking. Only name/type is required.

Please enter data online at https://www.trials.bham.ac.uk/STOPACEi or return form to: STOP-ACEi Office, Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK.

STOP-ACEi_CRF02_Baseline visit Page 8 of 10 Version 1.1, 19 Dec 2014

Common issues with form completion

...Changes to prescription of antihypertensive medications cont'd

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document. Current dose	Unit	Current freq.	Route
ACE inhibitor	✓						
ARB	✓						
CCB		✓	AMLODIPINE	5	mg	OD	O
Loop diuretic	✓						
Thiazide diuretic	✓						
Thiazide-like diuretic	✓						
K^+-sparing diuretic	✓						
Mineralocorticoid Receptor Antagonist e.g. spironolactone	✓						
Alpha blocker	✓						
Beta blocker		✓	BISOPROLOL	5	mg	OD	O.
Methyldopa	✓						
Moxonidine	✓						
Hydralazine	✓						
Other antihypertensive	✓						

ARB now ticked 'No' as patient was randomised to the stop arm of the trial

Fill in the rest of the table to show the medications the patient is still taking

Common issues with form completion

Pre-randomisation

Antihypertensive medications

Please indicate what antihypertensive medications the participant was taking at the point of randomi related changes.

Category	No	Yes	Type/brand name	Please see list of possible op Current dose	Unit
ACE inhibitor	☑	☐			
ARB	☐	☑	LOSARTAN	10	mg
CCB	☐	☑	AMLOPIDINE	5	mg
Loop diuretic	☑	☐			
Thiazide diuretic	☑	☐			
Thiazide-like diuretic	☑	☐			
K⁺-sparing diuretic	☑	☐			
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☑	☐			
Alpha blocker	☑	☐			
Beta blocker	☐	☑	BISOPROLOL	5	mg
Methyldopa	☑	☐			
Moxonidine	☑	☐			
Hydralazine	☑	☐			
Other antihypertensive	☑	☐			

(**Page 7** Baseline Visit CRF)

After being randomised to the stop arm of the trial

...Changes to prescription of antihypertensive medications cont'd

Category	No	Yes	Type/brand name	Please see list of possible opt Current dose	Unit
ACE inhibitor	☑	☐			
ARB	☑	☐			
CCB	☐	☑	AMLOPIDINE	5	mg
Loop diuretic	☑	☐			
Thiazide diuretic	☑	☐			
Thiazide-like diuretic	☑	☐			
K⁺-sparing diuretic	☑	☐			
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☑	☐			
Alpha blocker	☑	☐			
Beta blocker	☐	☑	BISOPROLOL	5	mg
Methyldopa	☑	☐			
Moxonidine	☑	☐			
Hydralazine	☑	☐			
Other antihypertensive	☑	☐			

(**Page 8** Baseline Visit CRF)

Common issues with form completion

The following results and assessments are only required at **baseline** and then again at **months 12, 24 and 36:**

- Weight
- C-reactive Protein (CRP)
- Sample Tracking
- Six-Minute Walk Test
- 12-Lead ECG
- KDQOL-SF questionnaires

STOP-ACEi website

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STOP-ACEi

STOP-ACEi is a national multi-centre randomised controlled trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease.

Trial details

Full Title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

Short Title: The STOP-ACEi Trial

Aim of the study: To test the hypothesis that stopping treatment with ACEi, ARB or a combination of both, compared with continuing on these treatments, improves or stabilises renal function in patients with progressive stage 4 or 5 Chronic Kidney Disease (CKD).

Study design: Open-label randomised controlled trial (RCT).

Sample size: 410 patients will be recruited into the study (205 in each arm) over a 2 year period.

Study Duration: The accrual period is for 2 years and all patients will be followed up for 36 months. The end of trial will be 6 months after the last data capture. The total study duration is 6 years.

Timeframes: NIHR/MRC EME programme grant start date: 1st February 2014. Trial set up will take place in 6 months, recruitment will take 24 months, all patients will be followed up for 36 months and 6 months has been allocated for data analysis and report writing. We aim to recruit the first participant in April/May 2014.

Chief Investigator: Prof Sunil Bhandari

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STOP-ACEi Protocol v3.0 (14th May 2014)

STOP-ACEi Online Randomisation and Data Entry

Contact the STOP-ACEi trial team

STOP-ACEi website

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Trial Documentation

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These documents are for use by collaborators involved in the STOP-ACEi trial. They are the property of the University of Birmingham and Hull and East Yorkshire Hospitals NHS Trust and do not constitute any form of advice to participants.

Please see links below to download STOP-ACEi documentation.

STOP-ACEi Protocol and REC-approved study documents

Open all sections

STOP-ACEi Protocol

STOP-ACEi Protocol, V3.0, 14th May 2014

STOP-ACEiPIS, GP Letters & Consent Form

STOP-ACEi Participant Information Sheet, V2.2, 28th January 2014

STOP-ACEi Participant Consent Form, V3.0, 14th May 2014

STOP-ACEi GP Letter - Treatment Continuation, V2.0, 6th January 2014

STOP-ACEi GP Letter - Treatment Discontinuation, V2.0, 6th January 2014

STOP-ACEi Other REC-approved documentation

STOP-ACEi Letter to accompany PIS, V1.0, 1st November 2013

STOP-ACEi Participant Advice Letter - Treatment Continuation, V1.0, 1st November 2013

STOP-ACEi Participant Advice Letter - Treatment Discontinuation, V1.0, 1st November 2013

STOP-ACEi Participant Diary, V1.0, 1st November 2013

STOP-ACEi Clinic Poster, V2.0, 6th January 2014

STOP-ACEi Advertising Text, V1.0, 1st November 2013

Version history

List of current documents and amendment log, last updated 11 Dec 2014

STOP-ACEi CRFs and KDQOL-SF™ questionnaire

STOP-ACEi website

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Recruitment

Last updated 23 April 2015

STOP-ACEi is open to recruitment.

STOP-ACEi aims to recruit 410 patients over a period of 2 years from approximately 20 centres across the UK.

Date first participant randomised	11 Jul 2014
Total recruitment to date	49
Total number of centres with full approval to take part in STOP-ACEi	18

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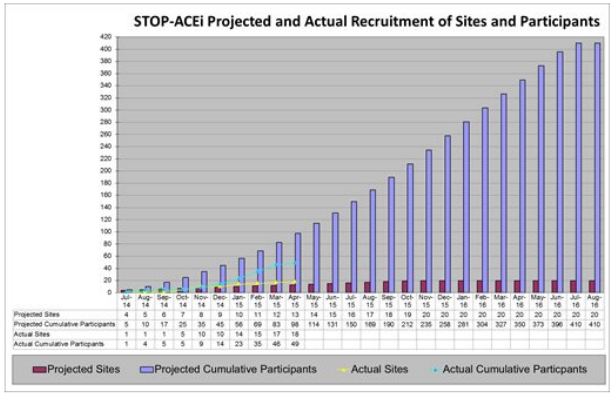
STOP-ACEi Patient Recruitment



Click here for a larger image of the recruitment graph.

STOP-ACEi Patient Recruitment by Centre

Contact details

Trial website:	www.birmingham.ac.uk/STOPACEi
Online Randomisation and data entry system:	www.trials.bham.ac.uk/STOPACEi
E-mail:	STOPACEi@bham.ac.uk
Telephone:	0121 415 9133
Fax:	0121 415 9135
Post:	Birmingham Clinical Trials Unit, School of Health & Population Sciences Public Health Building University of Birmingham Edgbaston B15 2TT
STOP-ACEi staff:	Marie Valente, Trial Coordinator Jamie Godsall, Data Manager Liz Brettell, Renal Trials Manager

Questions & Suggestions

Questions & Suggestions

If you have a question, suggestion or anything you would like discussed during the open discussion session (14:15-15:00) please write it in the space below and then post it in the questions box.

.....

.....

.....

.....

Name (optional): .....

If we don't get chance to discuss your question we will contact you after the event.