

Data Collection & Management

Investigator Meetings
1st and 2nd September 2016 - London and Leeds



Jamie Godsall
Data Manager, BCTU

UNIVERSITY OF
BIRMINGHAM



Hull and East Yorkshire Hospitals
NHS Trust





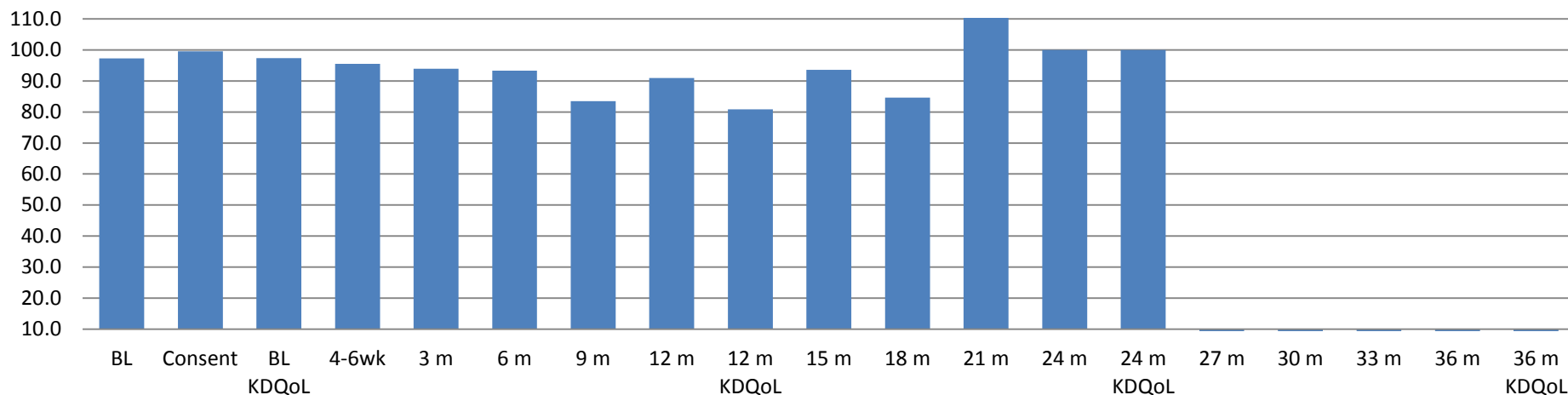
CRF return rates

Form	Time point	Forms expected	Forms received	Percentage received
Baseline	BL	228	222	97.2
Consent	Consent	228	227	99.6
KDQOLSF	BL KDQoL	228	222	97.4
Phone call	4-6wk	215	205	95.5
Follow Up	3 m	198	186	93.9
Follow Up	6 m	170	159	93.3
Follow Up	9 m	139	116	83.5
Follow Up	12 m	96	87	91.0
KDQOLSF	12 m KDQoL	94	76	80.9
Follow Up	15 m	52	49	93.6
Follow Up	18 m	26	22	84.6
Follow Up	21 m	5	7	140.0
Follow Up	24 m	1	1	100.0
KDQOLSF	24 m KDQoL	1	1	100.0
Follow Up	27 m	0	0	0
Follow Up	30 m	0	0	0
Follow Up	33 m	0	0	0
Follow Up	36 m	0	0	0
KDQOLSF	36 m KDQoL	0	0	0
Totals		1681	1580	94.0

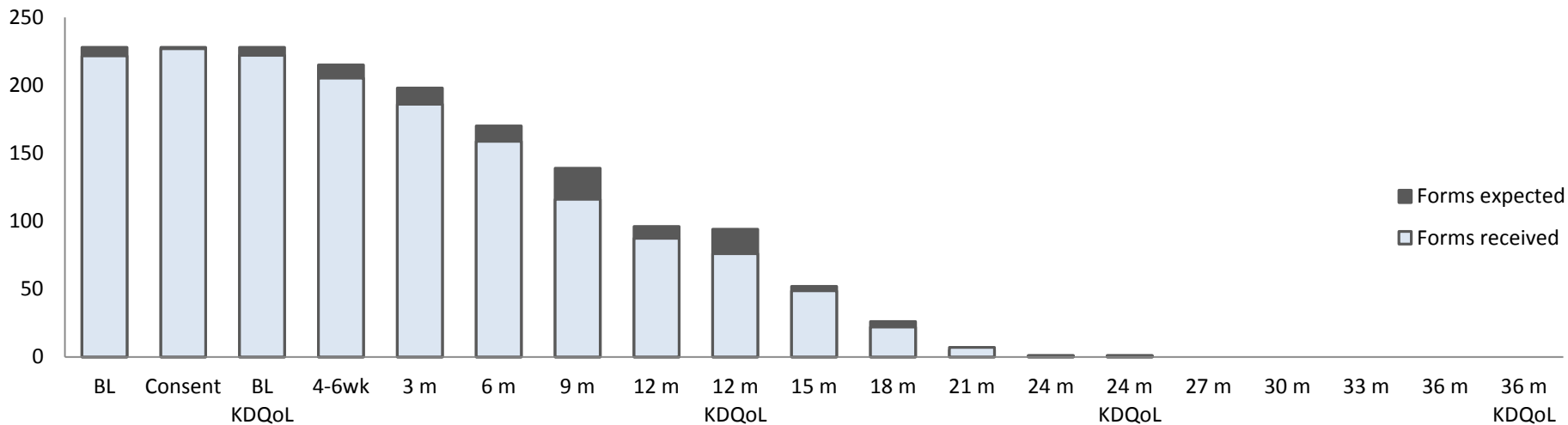


CRF return rates

Percentage of Expected Forms Received



Number of Expected Forms Received






Common problems with ICFs

Trial ID not completed

TO BE PRINTED ON LOCAL TRUST HEADED PAPER



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

- I confirm that I have read and understood the information sheet for the STOP-ACEi trial (version 3.0, dated 10th December 2014). I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily. ☐
- 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. ☐
- 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. ☐
- 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. ☐
- I agree that a copy of this consent form will be faxed to the BCTU. ☐
- I understand that my GP will be informed of my participation in the STOP-ACEi trial. ☐
- I agree that I may be contacted by the research team in the future regarding further research that is linked to this study. ☐
- 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.

- 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. ☐
- 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/mm/yyyy) _____ Signature _____

Name of Researcher _____ Date (dd/mm/yyyy) _____ Signature _____

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

Version 3.1, 24 March 2015
Page 1 of 2

ICF not on headed paper

Boxes ticked instead of initialled

Some required boxes not initialled

Clinician counter-signing ICF not on del. log.

Clinician counter-signing ICF on different date

Missing signatures / dates

Incorrect version no.



Common problems with ICFs

- Participant consent forms should either be faxed or emailed to our NHS email address.



stop.ace@nhs.net



0121 415 9135



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
- Don't forget KDQOL-SF questionnaires



CRFs and data entry

- Data should be entered directly into online system – will check for errors / omissions

Last Login date: 15-Aug-2016

STOP-ACEi

HOME PATIENTS EGFR CALCULATOR ADMINISTRATION HELP TRIAL WEBSITE

Patients: [Find patient](#) | [Patient Form](#) | Baseline Form - Pt.1

Baseline Form: : CONTINUE ACEi and/or ARB treatment

[BASIC ASSESSMENTS](#) | [LAB ASSESSMENTS](#) | [SAMPLE TRACKING](#) | [WALK TEST](#) | [ADMIN - VIEW AUDIT](#) | [ADMIN - VIEW CHANGES](#)

Notes specific to a form from the BCTU

Notes

Has this form been checked by BCTU Trial Team ☐

Admin lock this form? (this will prevent non-admin users from being able to edit the form) ☐

Date form was completed (dd-mmm-yyyy)

Smoking status:

Alcohol intake:

Height (in cm)

Weight (in kg)

Systolic BP (mmHg)

Diastolic BP (mmHg)

[EDIT](#) | [SUBMIT](#) | [SAVE](#) | [UNDO](#) | [DELETE](#) | [CHECK OUT](#)

Form Status: Data Entry In Progress - Locked

There are 26 queries for this form

- "Basic Assessments : Date form was completed (dd-mmm-yyyy)" has not been answered
- "Basic Assessments : Smoking status:" has not been answered
- "Basic Assessments : Alcohol Intake:" has not been answered
- "Basic Assessments : Height (in cm)" has not been answered
- "Basic Assessments : Weight (in kg)" has not been answered
- "Basic Assessments : Systolic BP (mmHg)" has not been answered
- "Basic Assessments : Diastolic BP (mmHg)" has not been answered
- "Lab Assessments : Serum Creatinine µmol/L:" has not been answered
- "Lab Assessments : Sodium mmol/L" has not been answered and is important

- Please keep originals of CRFs at site.
- You should have corresponding source data which must tally with everything submitted on the CRF.



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>



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

There have been a number of six-minute walk tests and questionnaires missed at the month 12 annual follow-ups. This data is important to the trial and should be obtained if possible.



Common issues with form completion

Lab Assessments

If a result is missing please leave the field blank.

PAGE 1 LAB ASSESSMENTS ADMIN - VIEW AUDIT ADMIN - VIEW CHANGES

Serum Creatinine $\mu\text{mol/L}$: 451

Biochemical profile

Sodium mmol/L	137
Potassium mmol/L	4.7
Bicarbonate mmol/L	21.7
Calcium mmol/L	2.10
Phosphate mmol/L	1.71
Alkaline phosphatase U/L	130
Albumin g/L	30
Total protein g/L	0
Alanine transferase U/L	15

Full blood count

Haemoglobin g/L	111
Platelets $\times 10^9/\text{L}$	121

Urinary PCR or ACR by early morning spot urine

PCR or ACR value given	PCR
Urinary PCR mg/mmol	744

EDIT SUBMIT SAVE UNDO DELETE CHECK OUT

Result not available. Field should be left blank:



Common issues with form completion

Add notes to minimise queries. Note boxes can be found on each part of the eCRF.

PAGE 1 LAB ASSESSMENTS ADMIN - VIEW AUDIT ADMIN - VIEW CHANGES

Notes specific to a form from the BCTU

No protein result available from this visit. Test was missed.

Notes

Has this form been checked by BCTU Trial Team

Admin lock this form? (this will prevent non-admin users from being able to edit the form)

Date form was completed (dd-mmm-yyyy) 17-Aug-2016

Has the participant died since the last trial visit? (If Yes, please complete and submit an SAE form) No

Is the participant willing to continue in the study? Yes

Has the participant withdrawn from the study? No

Basic Assessments

Systolic BP (mmHg) 112

Diastolic BP (mmHg) 80

EDIT SUBMIT SAVE UNDO DELETE CHECK OUT



Common issues with form completion

Add notes to minimise queries. Note boxes can be found on each part of the eCRF.

Use notes to tell us that a medication has stopped or a dose has been changed:

Notes

Allopurinol has been stopped since the last trial visit.
Ramipril dose increased to 10mg daily



A lab result is from a different date to the assessment:

Notes

Urinary PCR result from 2 weeks prior to trial visit (22-May-2016)



You're not sure of something:

Notes

Unsure if patient was seen in primary care so box left blank



Notes are really helpful to me and help to minimise queries.



Common issues with form completion

Please complete all drop down boxes.

BASIC ASSESSMENTS	CKD AETIOLOGY	CARDIOVASCULAR EVENTS	HEART FAILURE	MED HISTORY	ADMIN - VIEW AUDIT	ADMIN - VIEW CHANGES
Please indicate all conditions the patient has a known history or current diagnosis of. Heart failure, stroke and MI should be recorded in the previous sections						
Please indicate all conditions the patient has a known history or current diagnosis of.						
Other Cardiovascular Disease				Yes		
Diabetes				Yes		
Malignancy						
Gastrointestinal						
Musculoskeletal or connective tissue disorders						
Infection						
Pulmonary Disease						
Other				Yes		
Form Status: Data Entry In Progress						
There are 6 queries for this form						
"Med History : Malignancy" has not been answered						
"Med History : Gastrointestinal" has not been answered						
"Med History : Musculoskeletal or connective tissue disorders" has not been answered						
"Med History : Infection" has not been answered						
"Med History : Pulmonary Disease" has not been answered						
Baseline Medical History Form "Page 1 : Condition category" has not been answered						

The system will query missing data.



Common issues with form completion

A lot of queries are around medications with no corresponding medical condition. Please ensure that the patient's full medical history is present at baseline and new conditions are added as the trial progresses.



Common issues with form completion

PAGE 1	MEDICATION	ANTIHYPERMEDIATIONS	CONCOMITANT MEDICATIONS	COMPLIANCE	ECHOCARDIOGRAM	AD
Other concomitant medications						
Is the participant currently taking any other medications?				Yes <input type="checkbox"/>		
Statin				No <input type="checkbox"/>		
Digoxin				No <input type="checkbox"/>		
Nitrate				No <input type="checkbox"/>		
Fibrate				Yes <input type="checkbox"/>		
Ezetimibe				No <input type="checkbox"/>		
Aspirin				No <input type="checkbox"/>		
Bicarbonate				No <input type="checkbox"/>		
Sulphonylurea, e.g. glicazide				No <input type="checkbox"/>		
GLP-1 analogues/agonists, e.g. liraglutide, exenatide				No <input type="checkbox"/>		
Clopidogrel				No <input type="checkbox"/>		
Warfarin				No <input type="checkbox"/>		
Phosphate Binders				No <input type="checkbox"/>		
Calcium/Vitamin D				No <input type="checkbox"/>		
Bisphosphonate				No <input type="checkbox"/>		
Prednisolone				Yes <input type="checkbox"/>		
Metformin				No <input type="checkbox"/>		
Sirolimus				No <input type="checkbox"/>		
SGLT2 inhibitor, e.g. dapagliflozin				No <input type="checkbox"/>		
Mycophenolate mofetil (MMF)				No <input type="checkbox"/>		
Ciclosporin				No <input type="checkbox"/>		
Cyclophosphamide				No <input type="checkbox"/>		
Azathioprine				No <input type="checkbox"/>		
Tacrolimus				No <input type="checkbox"/>		
Methotrexate				No <input type="checkbox"/>		
NSAIDs				No <input type="checkbox"/>		
Thiazolidinedione/glitazone				Yes <input type="checkbox"/>		
DPP-4 inhibitor (incretins) e.g. sitagliptin, vildagliptin				No <input type="checkbox"/>		
Other Concomitant Med 1:				Yes <input type="checkbox"/>		
Other Concomitant Med 1: Specify				Allopurinol		

Hypercholesterolemia

Polymyalgia rheumatica

Diabetes Type 2

Gout



Common issues with form completion

Antihypertensive Medications at Baseline

If the patient has been randomised to discontinue ACEi/ARB the pre-randomisation and post-randomisation tabs should be completed as follows:

Pre-randomisation:

Baseline Form Pt 3: [REDACTED] : DOB: [REDACTED] : DISCONTINUE ACEi and/or ARB treatment

MEDICATIONS **ANTIHYPER-RAND** ANTIHYPER-POST-RAND CONCOM MEDS 12-LEAD ECG ECHOCARDIOGRAM ADMIN - VIEW AUDIT

ADMIN - VIEW CHANGES

Please indicate what antihypertensive medications the participant was taking at the point of randomisation, i.e. before any trial-related changes. All patients should have at least one ACEi or ARB listed

Add details about antihypertensive medication in the grid below, to do this first click on "Save" below then click "Add" in Antihypertensive medication (pre-randomisation)

Category	Type	Dose	Unit	Frequency	
					Add
ACE Inhibitor	Ramipril	10.00	mg - Milligram	Daily	View
CCB	Amlodipine	5.00	mg - Milligram	Daily	View

EDIT SUBMIT SAVE UNDO DELETE CHECK OUT

Form Status: Submitted - Complete

There are 0 queries for this form



Common issues with form completion

Antihypertensive Medications at Baseline

Post-randomisation:

Baseline Form Pt 3: : **DOB:** : **DISCONTINUE ACEi and/or ARB treatment**

MEDICATIONS **ANTIHYPER- RAND** **ANTIHYPER- RAND** **CONCOM MEDS** **12-LEAD ECG** **ECHOCARDIOGRAM** **ADMIN - VIEW AUDIT**

ADMIN - VIEW CHANGES

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation?
E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARB's)

Yes

Please indicate all antihypertensive medications the participant was prescribed following randomisation in the grid below, including any new drugs AND drugs the patient is continuing to take. To do this first click on "Save" then click "Add".

Category	Type	Dose	Unit	Frequency	
CCB	Amlodipine	5.00	mg - Milligram	Daily	Add View

EDIT **SUBMIT** **SAVE** **UNDO** **DELETE** **CHECK OUT**

Form Status: Submitted - Complete
There are 0 queries for this form

Patient has stopped taking their ACEi after randomisation

ACEi no longer listed and Amlodipine continues to be taken at the same dose



Common issues with form completion

Antihypertensive Medications at Baseline

Please **do not** enter a medication that has been stopped with a '0' dose

Post-randomisation:

Baseline Form Pt 3: [REDACTED] DOB: 0 [REDACTED] DISCONTINUE ACEi and/or ARB treatment

[MEDICATIONS](#) [ANTIHYPER- RAND](#) [ANTIHYPER POST-RAND](#) [CONCOM MEDS](#) [12-LEAD ECG](#) [ECHOCARDIOGRAM](#) [ADMIN - VIEW AUDIT](#)
[ADMIN - VIEW CHANGES](#)

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation?
E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARB's)

Please indicate all antihypertensive medications the participant was prescribed following randomisation in the grid below, including any new drugs AND drugs the patient is continuing to take.
To do this first click on "Save" then click "Add".

Category	Type	Dose	Unit	Frequency	
ACE Inhibitor	Ramipril	0.00			Add View
CCB	Amlodipine	5.00	mg - Milligram	Daily	View

[EDIT](#) [SUBMIT](#) [SAVE](#) [UNDO](#) [DELETE](#) [CHECK OUT](#)

Form Status: Data Entry In Progress
+ There are 3 queries for this form





Common issues with form completion

Differences between trial visits

Queries are often raised about differences between trial visits with no explanation (e.g. no note added, no new medical condition, no SAE or adverse event).

MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM MEDS 12-LEAD ECG ECH
ADMIN - VIEW CHANGES

Other concomitant medications

Is the participant currently taking any other medications? Yes

Statin Yes

Digoxin No

Nitrate No

Fibrate No

Ezetimibe Yes

Aspirin Yes

Bicarbonate Yes

Sulphonylurea, e.g. glicazide No

GLP-1 analogues/agonists, e.g. liraglutide, exenatide No

Clopidogrel No

Warfarin No

Phosphate Binders No

Calcium/Vitamin D Yes

Bisphosphonate No

Prednisolone No

MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM MEDS 12-LEAD ECG
ADMIN - VIEW CHANGES

Other concomitant medications

Is the participant currently taking any other medications? Yes

Statin Yes

Digoxin No

Nitrate No

Fibrate No

Ezetimibe Yes

Aspirin No

Bicarbonate No

Sulphonylurea, e.g. glicazide No

GLP-1 analogues/agonists, e.g. liraglutide, exenatide No

Clopidogrel No

Warfarin No

Phosphate Binders No

Calcium/Vitamin D Yes

Bisphosphonate No

Prednisolone No



Common issues with form completion

Please remember to submit eCRFs when completed

This lets me know that you have finished data entry and the form can be checked.

Platelets x10 ⁹ /L	161
Urinary PCR or ACR by early morning spot urine	
PCR or ACR value given	PCR
Urinary PCR mg/mmol	150
<div>EDIT SUBMIT SAVE UNDO DELETE CHECK OUT</div>	

You can check forms out to edit after they have been submitted (as long as I haven't locked them).

EDIT	SUBMIT	SAVE	UNDO	DELETE	CHECK OUT
------	--------	------	------	--------	-----------

↓

EDIT	SUBMIT	SAVE	UNDO	DELETE	Please give reason for checkout: Data entry	CHECK OUT
------	--------	------	------	--------	---	-----------

↓

EDIT	SUBMIT	SAVE	UNDO	DELETE	CHECK OUT
------	--------	------	------	--------	-----------



STOP-ACEi website



UNIVERSITY OF
BIRMINGHAM

[Alumni](#) [Working here](#) [Events](#) [Visit](#)

[Study](#) [Research](#) [International](#) [Business](#) [News](#) [About us](#)



[Home](#) > [Research](#) > [Research activity](#) > [Research in the College of Medical and Dental Sciences](#) > [Birmingham Clinical Trials Unit](#) > [Current Trials](#) > [STOPACEi](#)

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.

In 'STOPACEi'

> [Birmingham Clinical Trials Unit \(BCTU\)](#)

> [STOPACEi](#)

> [For Investigators](#)

> [For Trial Participants](#)


> [News and events](#)

> [Publications](#)

> [Contact us](#)




STOP-ACEi website

 UNIVERSITY OF BIRMINGHAM

Alumni Working here Events Visit

Study Research International Business News About us



Home > Research > Research activity > Research in the College of Medical and Dental Sciences > Birmingham Clinical Trials Unit > Current Trials > STOPACEi > For investigators > Trial Documentation

Trial Documentation

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.

Open all sections

STOP-ACEi Protocol and REC-approved study documents

STOP-ACEi Protocol
[STOP-ACEi Protocol, V3.0, 14th May 2014](#)
[MRC START in STOP-ACEi Protocol, V1.0, 10th December 2014](#)

STOP-ACEi PIS, GP Letters & Consent Form
[STOP-ACEi Participant Information Sheet, V3.0 Standard, 10th December 2014](#)
[STOP-ACEi Participant Consent Form, V3.1, 24th March 2015](#)
[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, V2.0 Standard, 10th December 2014](#)
[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 14th August 2015](#)

STOP-ACEi CRFs and KDQOL-SF™ questionnaire

In 'For Investigators'
> For Investigators
> Trial Documentation
> Recruitment
> Participating Centres
> Meetings
> Newsletters
> FAQs
[Back to 'STOPACEi'](#)



STOP-ACEi website



UNIVERSITY OF
BIRMINGHAM

[Study](#) [Research](#) [International](#) [Business](#) [News](#) [About us](#)

[Alumni](#) [Working here](#) [Events](#) [Visit](#)



[Home](#) > [Research](#) > [Research activity](#) > [Research in the College of Medical and Dental Sciences](#) > [Birmingham Clinical Trials Unit](#) > [Current Trials](#) > [STOPACEi](#) > [For Investigators](#) > [Recruitment](#)

Recruitment

Last updated 18 August 2016

STOP-ACEi is open to recruitment. We aim to recruit 410 patients over a period of 2 years from approximately 20 centres across the UK.

Overview

Date first participant randomised

11 Jul 2014

Total recruitment to date

230

Total number of centres with full approval

33

In 'For Investigators'

> [For Investigators](#)

> [Trial Documentation](#)

> [Recruitment](#)

> [Participating Centres](#)

> [Meetings](#)

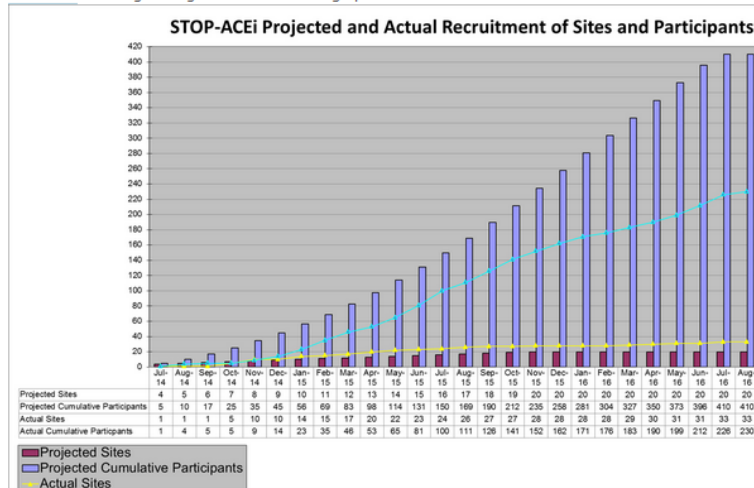
> [Newsletters](#)

> [FAQs](#)

< [Back to 'STOPACEi'](#)

STOP-ACEi Patient Recruitment

[Click here](#) for a larger image of the recruitment graph.





STOP-ACEi Twitter

 Join over 100 other Twitter users and
Follow us @STOPACEi_trial



The screenshot shows the Twitter profile of the STOP-ACEi Trial (@STOPACEi_trial). The profile picture is the STOP-ACEi logo. The bio states: "A clinical trial of ACE inhibitor and ARB withdrawal in patients with advanced CKD. This project is funded by the EME Programme, an MRC and NIHR partnership." The location is Birmingham, England, and the website is birmingham.ac.uk/stopacei. The account was joined in October 2015. The stats show 67 tweets, 102 following, 107 followers, and 13 likes. The tweets section shows three tweets:

- Tweet 1:** STOP-ACEi Trial @STOPACEi_trial · Aug 18
Thank you to the renal team @SalfordRoyalNHS who have recruited 2 new patients into #STOPACEi in August. We now have 230 participants.
- Tweet 2:** STOP-ACEi Trial @STOPACEi_trial · Aug 10
Remember to register for one of the #STOPACEi investigator meetings - 1st & 2nd Sep 2016: birmingham.ac.uk/stopacei/meeti... @UKRenalResearch
- Tweet 3:** STOP-ACEi Trial @STOPACEi_trial · Aug 3
Remember to register for the #STOPACEi investigator meetings 2016. All investigators and research staff welcome: birmingham.ac.uk/stopacei/meeti...



STOP-ACEi Twitter



@STOPACEi_trial



STOP-ACEi Trial @STOPACEi_trial · Jun 14

We are now half way there with patient recruitment for #STOPACEi! Well done to the team @SheffieldHosp for recruiting the 205th patient.



1



6



Remember to register for one of the #STOPACEi investigator meetings - 1st & 2nd Sep 2016: birmingham.ac.uk/STOPACEi/meeti... @UKRenalResearch



STOP-ACEi Trial @STOPACEi_trial · Mar 16

#STOPACEi trial reaches the landmark of 180 patients! Thank you to all the patients and research teams.

RETWEETS

3

LIKES

3



2





Contact details

Trial website: www.birmingham.ac.uk/STOPACEi

Online randomisation & data entry: www.trials.bham.ac.uk/STOPACEi

E-mail: STOPACEi@bham.ac.uk
STOP.ACE@nhs.net

Telephone: 0121 415 9133

Fax: 0121 415 9135

Post: Birmingham Clinical Trials Unit
Public Health Building
University of Birmingham
Edgbaston
B15 2TT

STOP-ACEi staff: Marie Valente, Trial Coordinator
Jamie Godsall, Data Manager



Data Manager Training – Spot the difference

Is the participant currently on ESA treatment?	Yes ▼
Epoetin alfa (e.g. eprex)	No ▼
Epoetin beta (NeoRecormon®)	No ▼
Darbepoetin alfa (Aranesp®)	Yes ▼
Darbepoetin alfa: Dose	60.00
Darbepoetin alfa: Unit	mcg - Microgram ▼
Darbepoetin alfa: Frequency	Twice a day ▼
Darbepoetin alfa: Route	Subcutaneous ▼
Mircera	No ▼
Other	No ▼

Is the participant currently on ESA treatment?	Yes ▼
Epoetin alfa (e.g. eprex)	No ▼
Epoetin beta (NeoRecormon®)	No ▼
Darbepoetin alfa (Aranesp®)	Yes ▼
Darbepoetin alfa: Dose	600.00
Darbepoetin alfa: Unit	mg - Milligram ▼
Darbepoetin alfa: Frequency	Twice a day ▼
Darbepoetin alfa: Route	Subcutaneous ▼
Mircera	No ▼
Other	▼



Data Manager Training – Find the queries

Baseline Form Pt 3: : DOB: : **DISCONTINUE ACEi and/or ARB treatment**

MEDICATIONS ANTIHYP PRE-RAND **ANTIHYPER POST-RAND** CONCOM MEDS 12-LEAD ECG ECHOCARDIOGRAM ADMIN - VIEW AUDIT
ADMIN - VIEW CHANGES

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation? E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARB's)

Yes ▾

Please indicate all antihypertensive medications the participant was prescribed following randomisation in the grid below, including any new drugs AND drugs the patient is continuing to take.
To do this first click on "Save" then click "Add".

Category	Type	Dose	Unit	Frequency	
					Add
Beta blocker	Bisoprolol	5.00	mg - Milligram	Twice a day	View
CCB	Amlodipine	10.00	mg - Milligram		View
Loop diuretic	Furosemide	40.00	mg - Milligram	Daily	View
Thiazide-like diuretic	Indapamide		mg - Milligram	Daily	View
ACE Inhibitor	Ramipril	10.00	mg - Milligram	Daily	View

[EDIT](#) [SUBMIT](#) [SAVE](#) [UNDO](#) [DELETE](#) [CHECK OUT](#)

Form Status: Data Entry In Progress



Data Manager Training – Find the queries

BASIC ASSESSMENTS

LAB ASSESSMENTS

SAMPLE TRACKING

WALK TEST

ADMIN - VIEW AUDIT

ADMIN - VIEW CHANGES

No protein result for this patient. Test not done.

Notes

Admin lock this form? (this will prevent non-admin users from being able to edit the form)

Yes ▼

Date form was received (dd-mmm-yyyy)

04-Dec-2014

Date form was completed (dd-mmm-yyyy)

24-Nov-2014

Smoking status:

Ex-Smoker ▼

Alcohol intake:

None ▼

Height (in cm)

165.0

Weight (in kg)

82.80

Systolic BP (mmHg)

144

Diastolic BP (mmHg)

89



Data Manager Training – Find the queries

BASIC ASSESSMENTS

LAB ASSESSMENTS

SAMPLE TRACKING

WALK TEST

ADMIN - VIEW AUDIT

ADMIN - VIEW CHANGES

Serum Creatinine $\mu\text{mol/L}$:

663

Biochemical profile

Sodium mmol/L

136

Potassium mmol/L

Bicarbonate mmol/L

19.6

Calcium mmol/L

2.22

Phosphate mmol/L

1.59

Alkaline phosphatase U/L

66

Albumin g/L

36

Total protein g/L

0

Alanine transferase U/L

15



Before you leave

- Slides will be made available online
- Certificates / CPD credits
- Feedback forms
- Expenses forms