

Newsletter

Issue 2, January 2013

ERICA: The Evaluation of the Role of Inflammation in Chronic Airway Disease

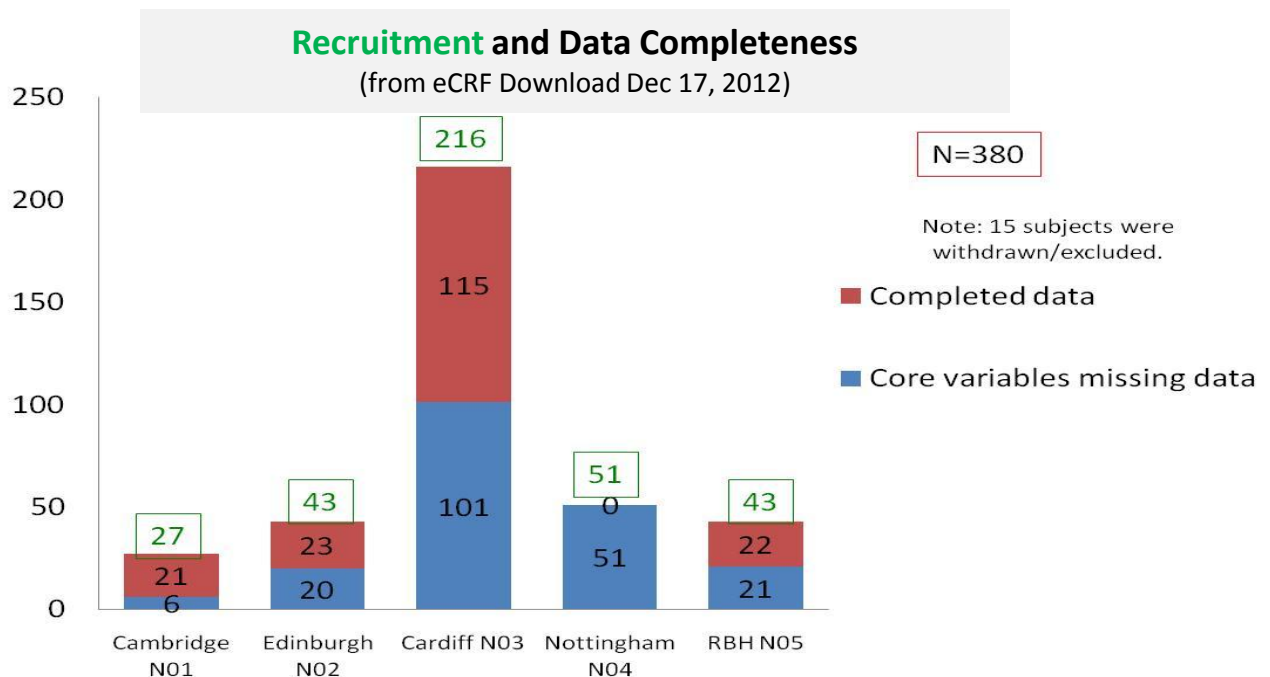
Multicentre Trial: Addenbrooke's Cambridge (Trial centre), Nottingham, Royal Brompton, Cardiff, and Edinburgh

**Getting Ready for INTERIM Analysis (n=400).
We need YOUR HELP to improve DATA completeness.**

This newsletter brings up important points that were discussed at the TSB Q5 Meeting in London earlier this month.

Recruitment:

We now have **387** patients in our study (as of Jan21, 2012). Many thanks to ALL investigators and research staff who have persisted with identifying eligible patients and recruiting them to our trial. We greatly appreciate your time and commitment!



Next data download: Feb 2013

Data collected at this point will be used for our interim analysis – please ensure ALL subjects have a completed dataset entered into eCRF

Trouble Hot Spots:

1. **Fibrinogen value:** If fibrinogen was not obtainable, please re-call patient to have another blood sample taken & document as a file note. Otherwise, the entire dataset collected will be OBSOLETE
2. **SNIP box:** eCRF only receives a max. of 2 digits, if more than 2, please leave box blank and enter number into the comment box
3. **PWV & QMVC:** should be within acceptable ranges and should not be marked as '0', if the data is questionable. Please seek your PI's opinion if concerned.
4. **Height and Weight:** If not obtainable from TANITA, please use next best method
5. **Patient Questionnaire Q11:** Please check 'NO' if the patients have not had any antibiotics or steroids in the last 6 or 12 months. If no response from patient, kindly phone to clarify
6. **Patient Questionnaire Q9 (MRC Score):** If patient ticks more than one box, please use the most serious one for eCRF.
7. **Follow Up Questionnaire: Q16-18.** These are *very important* questions for our analysis. Please ensure that these questions are completed, if not, kindly phone patient and complete.
8. Please, refrain from registering patients with a **pacemaker**, as PWV and Fat Free Mass will not be calculated and therefore cannot be used for data analysis.
9. **St. George's Respiratory Questionnaire:** Patient must complete in clinic, on his/her own, away from any distractions. Once finished, double check for completeness.

Core Variables for INTERIM Analysis:

Variables that need to be Complete

Height	hsCRP	PWV
Weight	Seated Systolic BP	QMVC
Fat Free Mass	Seated Diastolic BP	COPD age
4m Gait Speed	Seated HR	MRC Score
SPPB	Seated MAP	Smoking History
6 min walk test	Supine Systolic BP	Total Pack Years
Fibrinogen	Supine Diastolic BP	Cat Score
SNIP	BMI	Patient Qu. Q11 (antibiotics/steroids)

Updates:

- *Follow up questionnaires are crucial:* It is your responsibility to make sure all questionnaires are filled out and entered into eCRF.

Site	6mth Follow-Up Questionnaires		
	No sent out	No received	No entered into eCRF
Cambridge N01	12	10 (2 *)	10
Edinburgh N02	9	9	9
Cardiff N03	120	90 (30 *)	90
Nottingham N04	16	16	16
London N05	31	31	31
TOTAL	188	156	156

*** OUTSTANDING**

- *Time Table of 6 monthly Follow-Up Questionnaires* (see next page): I will continue to prepare mail merges for each site. Next Questionnaire Mail Out is **MARCH 2013**.
- A revised, sponsor-approved cover letter will now accompany the Follow-Up Questionnaire. We hope that this will help clarify the questions being asked and improve data completeness.

Month Patient Registered	September and March Mail Outs (Questionnaires to be sent 6 monthly for up to 2 years)						
Jan-June 2012	6mth to send Sept 2012	12 mth to send Mar 2013	18 mth to send Sept 2013	24 mth to send Mar 2014			
July-Dec 2012		6mth to send Mar 2013	12mth to send Sept 2013	18 mth to send Mar 2014	24 mth to send Sept 2014		
Jan-June 2013			6mth to send Sept 2013	12mth to send Mar 2014	18 mth to send Sept 2014	24 mth to send Mar 2015	
July-Oct 2013				6mth to send Mar 2014	12mth to send Sept 2014	18 mth to send Mar 2015	24 mth to send Sept 2015

- *Exacerbation Validation Phone Call:* Exacerbation is a very important criteria for data analysis. We would like to perform an exacerbation validation phone call to determine if patients are interpreting/answering the exacerbation questions (Q17&18 of Follow Up Qu) correctly. This will be done **ONE TIME ONLY**, on a small subset of patients from each site. We hope to have REC approval in time for the March Questionnaire Mail Out.

THANK-YOU EVERYONE!!

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