



# EARNEST Newsletter



Effect of A Reduction in GFR after Nephrectomy on Arterial Stiffness

Issue 1, 10<sup>th</sup> April 2014

## EARNEST

Welcome to the first EARNEST study newsletter. EARNEST is a multicentre clinical trial sponsored by the University of Cambridge and Cambridge University Hospitals Foundation Trust. The study is funded by a British Heart Foundation grant through the University of Birmingham.

Over the past 12 months we have gained regulatory and local approvals for the various sites. Overall we have started recruitment at 6 core sites (sites collect measurements that include ABPM, aPWV and isotopic GFR) and 1 non-core site (sites collect measurements that include ABPM).

## Site update

Core measurement site	PI	Start
1 Queen Elizabeth Hospital, Birmingham	John Townend	Jun-13
2 Addenbrooke's Hospital, Cambridge	Laurie Tomlinson	Jun-13
3 Southmead Hospital, Bristol	Charlie Tomson	Nov-13
4 Western Infirmary, Glasgow	Patrick Mark	Nov-13
5 University Hospital, Coventry	Nithya Krishnan	Feb-13
6 St George's Hospital, London	Debasish Banerjee	Apr-13
7 Central Manchester Hospital	Tunde Campbell	TBA
Non-core measurement sites	PI	Start
1 Sheffield Teaching Hospitals	Badri Shrestha	Nov-13
2 Belfast City Hospital, N. Ireland	Aisling Courtney	TBA

Recently, we welcomed Coventry and St George's, London to start recruitment for the EARNEST study.

We are awaiting the start of recruitment at Central Manchester and Belfast City Hospital.

To meet our target recruitment we are continuing to look for a few more sites. Currently, we estimate just over a 1 year of recruitment (Jun-14 – 15) and 1 year of follow-up.



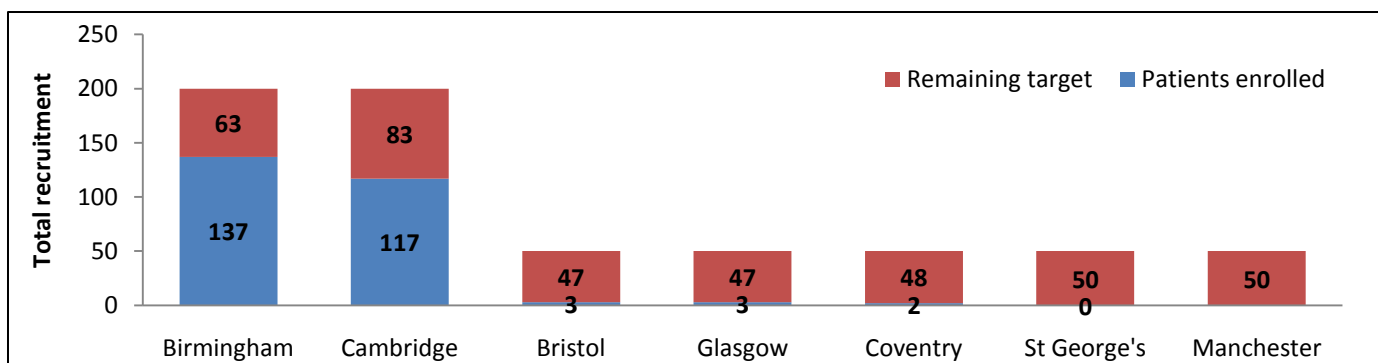
## Site recruitment update



The initial recruitment target for the EARNEST study (core sites) is 650 patients (325 donors and controls). We anticipate sites to recruit 1:1 donors and controls.

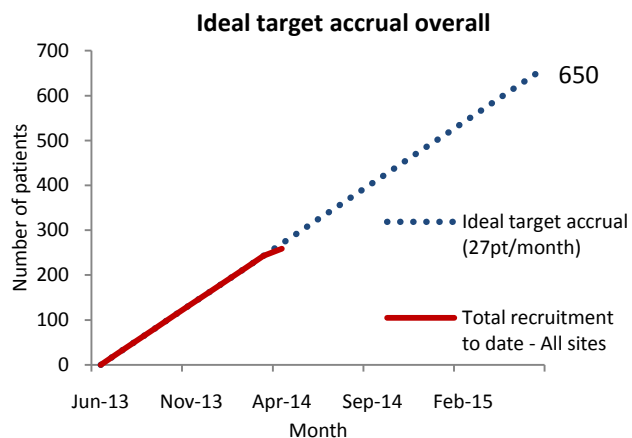
Birmingham and Cambridge have an overall target of 200 patients which includes some patients from the now closed CRIB Donor and KARMA studies. For all other sites we would hope that a target of 50 patients (25 donors and controls) would be achieved in the next year.

This equates to a realistic enrolment rate of 3 – 5 patients per month. The bar chart below shows the number of patients enrolled and the remaining target for each site (Manchester yet to start).



## Overall study recruitment update

	Target	Remaining target	Months remaining	Accrual rate /month
Birmingham	200	63	14	5
Cambridge	200	83	14	5
Bristol	50	47	14	3
Glasgow	50	47	14	3
Coventry	50	48	14	3
St George's	50	50	14	4
Manchester	50	50	~12	4
<b>Overall</b>	<b>650</b>			
<b>Donors/controls</b>	<b>325</b>			



## Data management update

### Patient identifiable information (PID) sheet

We would like to remind sites to submit their patient identifiable information sheet in the last week of every month to the EARNEST coordinators NHS.net address ([katan.patel@nhs.net](mailto:katan.patel@nhs.net)). This will allow us to collect up-to-date recruitment information to enter into the UKCRN database and enrol patients for long-term follow-up. Sending patient identifiable information to a NHS.net account is the recommended secure way to deal with transfer of sensitive data across centres.



### EARNEST CRFs and database

Recently we released version 2.0 of the EARNEST case report form (CRF). The CRF incorporates some minor corrections and additions since the last release.

For the EARNEST clinical trial, sites are expected to complete CRFs to document source data as required for the purposes of an audit trail. However, where a printout of the source data is available it is recommended that sites attach the printout to the relevant CRF page. For example, this would be ideal for blood results and the ABPM summary sheet. We hope that attaching source data printouts to CRFs will reduce the workload and potential transcription errors.

We hope to release the live version of the OpenClinica database in May 2014. We expect sites to continue to enter data firstly into the CRF to capture source data and then into the database as they go along.



### Up and coming events...

Release of the OpenClinica database to all EARNEST sites in May 2014.

The EARNEST newsletter will be released at regular intervals to update sites on progress and any important events. If your site has any suggestions then please do not hesitate to get in touch with the trial coordinator.

We hope to arrange an EARNEST Trial Steering Committee (TSC) meeting to include all sites in **Jun 2014**. More details to follow...



### EASTER break

We would like to thank sites for their continued effort in recruitment for the study.

We hope that everybody has a good break and see you all back soon...



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