# SPIRO-CKD Newsletter

**A Randomised Multicentre Open Label Blinded End Point Trial to Compare the Effects of Spironolactone to Chlortalidone on Left Ventricular Mass and Arterial Stiffness in Stage 2 and Stage 3 Chronic Kidney Disease**

**Summer 2015 Issue** | **May 2015**

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## Welcome to the Summer 2015 issue of the SPIRO-CKD Newsletter!

Welcome to the summer 2015 SPIRO-CKD Newsletter. There have been quite a few changes since the last issue; all four sites are now open to recruitment and we have approval to recruit patients with Stage 2 CKD in addition to those with Stage 3 CKD (more on that later).

UNIVERSITY OF BIRMINGHAM

## Message from the Chief Investigator

Dear Colleagues,

I would like to thank all investigators for their efforts on this study, recruitment has been slow but there is a glimmer of evidence that things are improving. The expanded eGFR criteria are bringing more patients within 'recruitment range' and colleagues at the Royal Free are within sight of randomising their first patients. Could I ask everybody to continue to search diligently for patients with stage 2 and 3 CKD; I know many patients with this 'mild' degree of renal disease are often discharged back to community care but there are many patients with more complex renal diagnoses and the chance of progression that remain in hospital care. Patients with quiescent vasculitic disease and polycystic disease are 2 good examples.

I am delighted to be able to say that the database and eCRFs are now online; more information on the website and database is available further on.

Best wishes,
Prof. Jon Townend

| Trial Design | Aims |
|---|---|
| Prospective, randomised, open-label, blinded-endpoint (PROBE) study design | • To assess the change between baseline and 40 weeks in arterial stiffness measured by carotid-femoral pulse wave velocity (PWV)<br>• To assess the change between baseline and 40 weeks in LV mass measured by cardiac magnetic resonance imaging (CMR) |

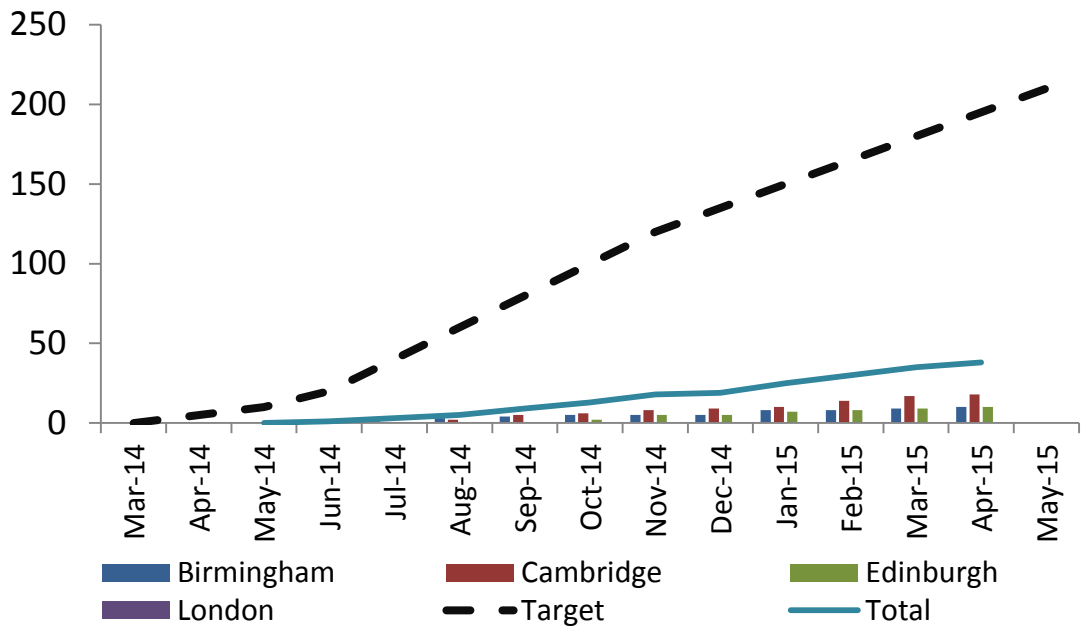
## Population

Eligible patients aged 18 years or over, who have a diagnosis of **stage 2** or stage 3 CKD (eGFR by 4 variable MDRD equation of **30-89** ml/min/1.73m$^2$), well controlled blood pressure (office reading of **<160/100** mmHg) and are on established (> 6 weeks) treatment with ACEi or ARBs.

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| • Aged over 18 years<br>• Diagnosis of **stage 2** or stage 3 CKD (eGFR by 4 variable MDRD of **30-89** ml/min/1.73m$^2$ on 2 occasions within the **9 months prior** to randomisation, at least 90 days apart)<br>• Patients with an office blood pressure reading of **<160 systolic and <100 mmHg** diastolic can be included at the discretion of investigating clinician.<br>• On established (>6 weeks) treatment with ACE inhibitors or ARBs.<br>• Clinically stable (no hospital admission or other significant acute illness within 3 months and no recent (<6 months) acute myocardial infarction or symptoms, or other evidence, of heart failure and/or left ventricular dysfunction)<br>• Written informed consent | • Diabetes mellitus<br>• Clinical evidence of hypovolaemia<br>• On current regular treatment with non-steroidal anti-inflammatory drugs, or other agents (except ACEi, ARB or low-dose aspirin) that might cause a reduction in GFR.<br>• Recent (<6 months) acute myocardial infarction or other major adverse cardiovascular event<br>• Established diagnosis of left ventricular dysfunction or heart failure<br>• Active malignant disease with a life expectancy of <5 years<br>• Previous hyperkalaemia (K+ ≥6.0 mmol/l without precipitating cause)<br>• Serum K+ > 5.0 mmol/l at entry<br>• Serum sodium <130 mmol/l at entry<br>• Atrial fibrillation on screening ECG<br>• Use of a thiazide or loop diuretic in the 6 weeks prior to enrolment<br>• Pregnancy |

## Trial Updates

**Recruitment to date**




### Amendment

In line with feedback from the December 2014 Trial Steering Committee Meeting, the first substantial amendment to the SPIRO-CKD protocol, proposing the inclusion of patients with Stage 2 CKD in addition to those with Stage 3 CKD and a relaxation of upper BP parameters, was submitted to the relevant regulatory bodies for review. The amendment was approved fully, earlier in the year.

A further amendment (SA2) was submitted during April and approved fully, in May. This amendment clarified that patients may be followed up by telephone if they do not respond to the initial invitation letter.

Please ensure that your investigator site files are up-to-date

### Online Randomisation and eCRF System is now live

Testing has been completed and the SPIRO-CKD randomisation system is now live. We will be contacting you shortly with log in details, after which time you will be able to randomise patients and enter patient visit data online. When you have your login details, to randomise patients into the trial, simply follow the on-screen instructions.

Please contact the SPIRO-CKD Trial Office for help with this system.

**Access the SPIRO-CKD online system at: www.trials.bham.ac.uk/spirockd**

### Website

We are very pleased to tell you that the SPIRO-CKD website has now gone live and can be found by typing www.birmingham.ac.uk/spirockd into your search engine. Here you'll be able to find general information about the trial and download trial documentation.

## Recruitment

As you'll see from the above figure, recruitment is still behind target. This is being closely monitored and will be discussed at the next Data Monitor Committee and Trial Steering Committee. Sites are reminded that they are invited to contribute to the TSC Meeting for an open discussion session (**2.30 – 3.00, 23rd June 2015**), teleconference facilities will be provided and an agenda sent out in due course.

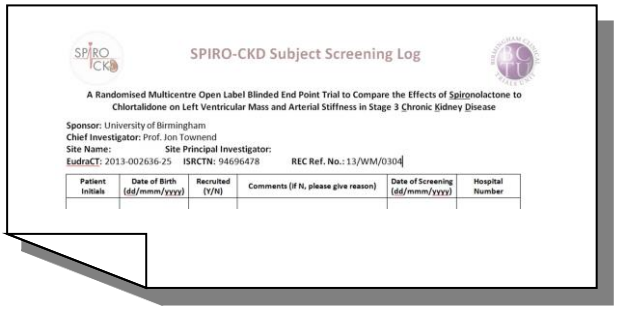

## Housekeeping – time for a Spring clean?

There have been many updates to trial documentation recently including the protocol, patient documentation and CRFs so can we ask that you take the time to ensure that all of your documents are up-to-date with previous versions marked as superseded.

Likewise, please can you ensure that your delegation logs are kept up-to-date (this includes crossing out members of staff who no longer work on the trial).

## Screening Logs

With patient recruitment still behind target, we're going to be monitoring screening closely to help identify any avoidable recruitment barriers. Please can you ensure that you continue send your completed, ANONYMISED screening logs to the SPIRO-CKD Trials Office at the end of each month? Information from screening logs will also be presented to the Trial Steering Committee



SPIRO-CKD Subject Screening Log

A Randomised Multicentre Open Label Blinded End Point Trial to Compare the Effects of Spironolactone to Chlortalidone on Left Ventricular Mass and Arterial Stiffness in Stage 3 Chronic Kidney Disease

Sponsor: University of Birmingham
Chief Investigator: Prof. Jon Townend
Site Name: Site Principal Investigator:
EudraCT: 2013-002636-25 ISRCTN: 94696478 REC Ref. No.: 13/WM/0304

| Patient Initials | Date of Birth (dd/mmm/yyyy) | Recruited (Y/N) | Comments (if N, please give reason) | Date of Screening (dd/mmm/yyyy) | Hospital Number |
|---|---|---|---|---|---|
| | | | | | |

## The SPIRO-CKD Trial Team

| Queen Elizabeth Hospital Birmingham | Birmingham Clinical Trials Unit | |
|---|---|---|
| **CI:** | **Trial Coordinator:** | **Data Manager:** |
| Prof. Jon Townend | Gemma Slinn | Hannah Lack |
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## SPIRO-CKD Trials Office:

**Website:** www.birmingham.ac.uk/spirockd
**E-mail:** spiro-ckd@trials.bham.ac.uk
**Telephone:** (0121) 415 8445
**Fax:** (0121) 415 9135

**Postal address:**

**SPIRO-CKD Trial Office**
**Birmingham Clinical Trials Unit (BCTU)**
School of Health & Population Sciences
College of Medical and Dental Sciences
Public Health Building
University of Birmingham
Edgbaston
Birmingham
B15 2TT

## Randomisation:

**Website:** www.trials.bham.ac.uk/spirockd

**Telephone:** 0800 953 0274
(Available 9am-5pm, Monday – Friday)

## Upcoming Trial Office Closures

BCTU will be closed for the late Summer Bank Holiday on the 31st August 2015.

The online randomisation system will still be accessible during these times.

**Thank you for taking the time to read the SPIRO-CKD Newsletter!**