

# William Harvey Clinical Research Centre

Newsletter January 2015



## UCLP Prime Site Report

The UCLP Quintiles Prime Site is the top recruiting Prime Site globally for the second year running. The Prime Site, coordinated from the WHRI Heart Centre, has continued to expand during 2014 across all NHS Trusts within the UCLP area.

The site improved upon 2013 performance with 805 patients recruited to all studies in 2014 (798 in 2013), significantly increased the number of studies open to enrolment (75), achieved a non enroller rate below target (13%); delivered quality above target (98%) and executed more contracts than any other site in the UK (n=48 - represents 1:6 Quintiles contracts executed in the UK - more than the other UK Prime Sites combined). So overall, fantastic performance!

The Prime Site program is a key part of the Quintiles global site management strategy to maximise delivery of commercial clinical trials across all therapeutic areas. The UCLP Prime Site initially established at QMUL was the world's first Prime Site and continues to set the standard for the other sites to follow.

# Revolutionary device found to lower blood pressure

A revolutionary device has been shown to significantly lower blood pressure among patients with uncontrolled high blood pressure, compared to those treated with usual drug measures. The research paper published today (23 January) in *The Lancet*, reports on the trial of the device. The device – developed by ROX Medical and named the ‘Coupler’ – is a paper clip sized implant which is inserted between the artery and vein in the upper thigh, in a procedure lasting around 40 minutes under local anaesthetic.

The trial was led by Dr Mel Lobo who is lead author of the *Lancet* paper and Principal Investigator of the study. Patients who participated in the trial were recruited from the Barts Blood Pressure Clinic. The devices were inserted by Dr Ajay Jain and co-ordinated by Jessry Veerapen at the London Chest Hospital. Patient follow-up and ongoing care was provided by Dr Manish Saxena, Anne Zak and Patrizia Ebano and the rest of the team at the Clinical Research Centre. The trial compared the effects of the Coupler versus usual medical treatment in 83 patients (with resistant high blood pressure that had not responded to at least 3 types of drug treatment) of whom 44 received the ROX Coupler therapy. Patients who received the Coupler experienced a significant and durable reduction in blood pressure. There was also a reduced number of hypertensive complications and hospital admissions for high blood pressure crises.

The Coupler also worked well among patients who had failed to respond to renal denervation (another new approach to treating high blood pressure), suggesting the Coupler targets different mechanisms of blood pressure control. However, patients who had not previously been treated with renal denervation experienced the same level or more of blood pressure reduction. In addition, unlike renal denervation, this new device-based treatment is fully reversible, immediate and pain-free.

However, the Coupler, like all therapies, did have a side effect. Around 29 percent of patients who received the Coupler did go on to develop leg swelling which meant another short procedure was needed to deal with this (usually a stent in the vein).

**Dr Lobo concludes:**

*"It's a little too early to begin applying these findings to routine clinical care at this stage. We need more research to explore the long-term effects of the Coupler, better understand its safety and understand more about how it works within the body. However, an International Registry is commencing early this year which means we will be able to continue offering patients with uncontrolled high blood pressure the option of Coupler treatment, as long as conventional measures to get their blood pressure down to target have failed."*

The trial was funded by ROX Medical and Dr Lobo's research is supported by Barts Charity.

## **Janssen Asthma study**

Congratulations to Dr Manish Saxena, Wai Yee James and team for being the highest recruiter globally with two other US sites on this study! This was a difficult study (Phase 2 trial) with a high screen failure rate for patients with uncontrolled and persistent asthma. The last subject was enrolled on 6 January 2015. This is a fantastic achievement for our team!

## **HAPPY London study**

As reported in the December Newsletter, the Happy London study is now in follow-up. The Chair of the NIHR/UKCRN National Cardiovascular Specialty Sub-group for Cardiovascular Prevention Professor Paul Leeson, has written to Professor Steffan Petersen and the team here at the CRC to congratulate us on our successful recruitment, and efficient and thorough conduct of this study. The study recruited to time and target!

## **International Clinical Trials Day: May 20**

The CRC is in the process of planning some activities to celebrate International Clinical Trials Day on Wednesday 20 May. This day is to celebrate James Lind's famous scurvy trial (widely considered to be the first ever clinical trial). Events will be publicised – watch this space!

## CRC staff profile: Dr Manish Saxena



Dr Manish Saxena is a Clinical Research Fellow at the Heart Centre. He has been working at the Centre since 2008. Manish's research interests are in the area of resistant hypertension. He is the Principal Investigator on a number of clinical trials currently being run at the centre including hypertension, CV outcome studies in high risk and diabetic patients, respiratory studies in asthma and COPD patients.

Manish has also worked on trials for device based treatments for hypertension such as the Symplicity HTN-2, EnligHTN II and ROX RH-02 studies with Dr Mel Lobo. These studies have resulted in two Lancet publications. One in 2010 and the second has just been published online (22 January).

Manish also works at the Barts Hypertension Clinic. He Chairs the London-Brent NRES Committee and is Vice-Chair of the London-Hampstead NRES Committee.