Cardiovascular Clinical Trials Unit: Update

As part of a large grant from the Barts Charity, funding has been awarded for a Cardiovascular Clinical Trials Unit to be set up for Barts. This will bring together the expertise needed to undertake a clinical trial from the William Harvey Clinical Research Centre, the Barts Heart Centre and the Cardiovascular Biomedical Research Unit along with funding for 5 new posts. This will create a UK CRC compliant Unit which will become a branch of the pre-existing Barts Clinical Trials Unit. We are currently working with the Barts CTU to set this up.

There will be many benefits to having a Cardiovascular CTU such as:

- Trials expertise will become internal to Barts
- Will enable us to grow our NIHR and BHF funded clinical research funding
- Will support all areas of the cardiovascular research programme across Barts and QMUL
- Will hopefully result in increased research funding!
The Cardiovascular CTU will provide expertise and advice in the following areas:

- Trial design, sample size and statistics
- Developing proposals and funding applications
- Project management
- Regulations and governance
- Patient and public involvement
- Quality management
- Database development
- Recruitment of patients (and staff for specific projects)
- Trial oversight and day to day management

There is a Cardiovascular CTU Project Group overseeing this. Membership of the group is as follows:

Interim Chair: Dr Vivienne Monk, CRC Manager
Professor Amrita Ahluwalia, WHRI Deputy Director
Professor Steffen Petersen, BHC Research Director
Professor Mark Caulfield, WHRI Co-Director
Dr David Collier, CRC Clinical Lead
Benoit Aigret, Head of Barts CTU
Dr Sam Mohiddin, Chair of BHS Peer Review Committee

The position of Director of the Cardiovascular CTU will shortly be advertised.

For any further information about the CV CTU please contact Vivienne Monk (v.monk@qmul.ac.uk).

**Study Updates**

**Kona Wave IV study**

This Phase II randomized sham controlled study of renal denervation for subjects with uncontrolled hypertension has recruited its first 8 patients who were treated in September. Sky news were on hand to report on this. The Sky piece was first broadcast at 6.30pm Saturday 26 September and thereafter throughout the evening. It featured an interview with Dr Mel Lobo.
(PI on the study), Dr Omar Dawood (from Kona Medical US) and a patient and a piece to camera in the treatment room.

Here is the link to the Sky news piece: [http://news.sky.com/video/1559453/blood-pressure-breakthrough](http://news.sky.com/video/1559453/blood-pressure-breakthrough)

We are still recruiting to this study and further treatments are being planned for December. People who wish to find out more and assess their suitability for the trial can contact Anne Zak at the William Harvey Heart Centre Clinical Research Centre on 0207 882 5657.

**Fifty-year old drug is best in resistant hypertension**

Resistant hypertension is a type of poor blood pressure which is difficult to control despite treatment with a combination of three drugs affects as many as 10% of patients and leaves them more likely to suffer a stroke or heart attack.

Dr David Collier, co-author of the report from the William Harvey Research Institute at QMUL said, “We enrolled most patients in this study and we’re delighted that there is now no doubt of what first choice should be for many patients with resistant hypertension.”
The PATHWAY-2 study which was funded by the British Heart Foundation and the National Institute for Health Research and published by the Lancet, showed that the diuretic, spironolactone was significantly more effective than other drugs at treating resistant hypertension.

Dr Manish Saxena, another of the report’s co-authors said that, “PATHWAY 2 unequivocally answers whether diuretic therapy with spironolactone is more effective at reducing blood pressure than doxazosin which acts to open arteries, or bisoprolol which reduces the output from the heart.”

This finding, together with hormone measurements in the patients, suggests that the predominant underlying cause of resistant hypertension is sodium retention.

Prof Mark Caulfield, co-principal investigator of the research, said, “A novel feature of this study was the use of an automated BP monitor in the clinic and at home across each treatment cycle. It is remarkable that nearly three quarters of patients with uncontrolled blood pressure saw a major improvement in their blood pressure on spironolactone.”

http://www.qmul.ac.uk/media/news/items/smd/163727.html

**TIME Treatment in the Morning versus Evening**

We have recently started recruiting patients for this new study.

For this study subjects should:
1. Be hypertensive (on medication).
2. Be taking their blood pressure medication OD.
3. Have internet access at their homes.

If prospective participants are happy they can register themselves online on [www.timestudy.co.uk](http://www.timestudy.co.uk) download the Participant Information Sheet and sign an electronic consent. After that they will be randomised to take their existing BP medication either in the morning or in the evening. They will then be monitored with online questionnaires by the University of Dundee.
When registering participants are asked where they heard about the study and if they choose ‘hospital or clinic’ they are then given a drop down list to choose what hospital they were provided the information by (Barts).

Let’s talk hearts

Let’s talk hearts seminars - the latest talk was held on 9th October at the Idea Store Whitechapel - one a series of free talks on heart health open to all.

The talks were given by Dr Dan Jones on ‘Nitrite: A natural way to reduce heart attacks’ and by Dr Steve Hamshere on ‘Stem Cells to repair damaged Hearts’.

If you are interested in attending Let’s talk hearts or if you have a heart topic you would like to speak about please contact letstalkhearts@qmul.ac.uk

To join the ‘Let’s talk hearts’ mailing list please email letstalkhearts@qmul.ac.uk or ring 07572 768985.

Barts and Queen Mary science festival 2016 - will be held on 6th July, further details to follow in due course.
Open to all but particularly aimed at secondary schools. For more information or if you are interested in helping in any way please contact sciencefestival@qmul.ac.uk

Please email j.batchelor@qmul.ac.uk