

Welcome to the Summer edition of the Clinical Trials and Evaluation Unit Bristol (CTEU) newsletter.

We have had a busy few months, with a number of studies in set-up and the early stages of recruitment. We will bring you more details of these in our newsletters.

We have also had a number of studies reach their recruitment targets which is fantastic news!

## Studies in Recruitment

	Study name	Recruitment to date
Adult cardiac surgery trials	Cortisol	60
Interventional cardiology trials	MR-Inform	100
Observational studies	ARCADIA	32
	Oxford Artery Study	129
	Prove (vein study)	608
Non-cardiovascular trials	AIRWAYS-2 (paramedics)	1208
	AIRWAYS-2 (patients)	405
	By-Band	215
	Bluebelle Phase A	172
	EVARREST	8

Recruitment figures as of July 2015

## Spotlight on: CARDIOMAN

Treatment of Barth Syndrome by CARDIOlipin MANipulation (CARDIOMAN).

Barth Syndrome is a life threatening genetic disease which affects young males. It is caused by abnormal fats (lipids) in the powerhouses of cells (mitochondria). Currently there is no treatment for Barth Syndrome apart from supportive care for the symptoms experienced.

Scientific research has shown that several medicines may improve the fat abnormalities in cells affected by Barth Syndrome. One is a drug called bezafibrate, which is already used in children and adults to lower blood fats and to treat other muscle diseases due to mitochondrial problems.

The purpose of this study is to see if bezafibrate is a safe and effective treatment for Barth Syndrome. The effect of bezafibrate will be compared to that of a placebo in a cross-over design (that is patients receive both bezafibrate and placebo).

This is a single centre study in patients attending the NHS National Barth Syndrome Service. A total of 18 males aged between six and 24 years currently attend the service each year. We anticipate that up to 12-15 patients will take part.

The results will be shared with American/European teams so that this work will have worldwide benefit.

The study is funded by the NIHR Efficacy and Mechanisms Evaluation (EME) funding stream.

## News

### The Cortisol study recruits its final patient!

The Cortisol study started recruitment in 2011 and recruited the final patient in June 2015; it has recruited 60 patients in total. There will be an update on the CTEU website when the results are published. A big thank you to all of the staff involved in the successful completion of recruitment for this study!

### Violet trial now open!

The Violet trial has now started recruiting at the Royal Brompton Hospital with more sites opening over the coming months. The trial compares different surgical techniques for lobectomy for lung cancer (video-assisted vs. open surgery).

### By-Band becomes By-Band-Sleeve!

The By-Band study, comparing gastric banding and gastric bypass, has been adapted to also include sleeve gastrectomy, another type of bariatric surgery. Sites have now started recruiting to all three operations. New sites are also being opened. Further information can be found on the study website <http://www.by-band-sleeve.bris.ac.uk/>

## Trials in set up




# Conferences

Several members of the unit are presenting at conferences throughout the year



In April, co-director Professor Barney Reeves presented findings from the Titre2 study at the British Society for Haematology 55th Annual Scientific Meeting, Edinburgh.

At the beginning of July, two of our team went to the Health Services Research Network conference in Nottingham, where they presented on the PIPA study, a study to evaluate the feasibility of setting up a UK multicentre prospective

cohort study to document cardiac MRI use in patients who undergo primary percutaneous coronary intervention.

Three of our statisticians took their work to the Young Statisticians Meeting in Cardiff, including work on a multi-centre bariatric surgery study (By-Band), a large multi-centre blood stream infections trial, and some of the work being done to develop study databases more efficiently.

We will also be presenting some of our work on the Echoes trial (a virtual ophthalmology trial) and on understanding relationships between different complications after cardiac surgery at the Royal Statistical Society meeting in Exeter in September.

In November, several members of the unit will be presenting at the 3rd International Clinical Trials Methodology Conference (ICTMC2015), Glasgow.

## Day in the life of a Trial Coordinator

Our Trial Coordinators are responsible for the management of activities related to the set up, day-to-day running and close out of clinical trials. They act as a main point of contact for queries from patients and other staff involved in a clinical trial. Below are some of the tasks that the CTEU Trial Coordinators would typically be involved in:

### SET-UP

- Obtain ethical approval, NHS approval and sponsorship for the trial
- Develop trial documentation
- Plan and carry out site initiation visits
- Work with database team and statisticians to develop CRFs and a database
- Set up a Trial Master File and site files



### RECRUITMENT

- Liaise with all staff involved in trial to ensure smooth running of the trial
- Resolve any queries from staff or patients
- Arrange trial related patient tests and visits
- Monitor progress and audit data collection
- Ensure all trial consumables are stocked and supplied



### ANALYSIS & REPORTING

- Work with research nurses and statisticians to resolve data queries
- Contribute to writing of study publications and dissemination of results
- Submit trial reports



## Airways-2 study now recruiting



**AIRWAYS-2 is a clinical study looking at the best way to manage the airway of patients who have had an out-of-hospital cardiac arrest – placing a breathing device (i-gel) into the back of the mouth or a breathing tube into the windpipe (intubation).**

The AIRWAYS-2 study, which is being funded by the National Institute for Health Research (NIHR) and coordinated by Bristol CTEU, will determine which airway management gives the best survival and recovery rates for patients. Currently, only one in 10 people who suffer a cardiac arrest outside of hospital will survive to make

a full recovery. There is now a real desire amongst paramedics and airways experts to find the best method to use to ensure a clear airway during an out-of-hospital cardiac arrest.

Adult patients who suffer a cardiac arrest, that is not caused by injury, and who are attended by an AIRWAYS-2 paramedic, will be enrolled automatically in the study.

However, they can opt out if an immediate family member, relative or close friend is present and tells the paramedic at the start of treatment that they do not wish to take part.

The trial is aiming to recruit over 9000 patients in a two year period. Four separate Ambulance trusts are involved incorporating 100 acute hospitals.

**For more information about the study visit [www.airways-2.bristol.ac.uk](http://www.airways-2.bristol.ac.uk) and the CTEU website [cteu.bris.ac.uk](http://cteu.bris.ac.uk)**

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