Newsletter

Clinical Trials and Evaluation Unit Bristol

Winter 2015

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

Through these newsletters, we aim to bring you updates about the progress of our trials and give you an overview of the variety of work that goes on at the CTEU.

Our multidisciplinary team work on a range of trials in cardiology, adult & paediatric cardiac surgery, general surgery, ophthalmology, observational studies and most recently, emergency medicine.

We look forward to working on new studies this year.

Trials in Recruitment

	Study	Recruitment to date
Adult cardiac surgery trials	Cortisol	49
	Pre-conditioning	120
	VeRDiCT	170
	Victory	15
Interventional cardiology trials	MR-Inform	81
Observational studies	ARCADIA	13
	Decision	198
	Oxford Artery Study	106
	PIPA	1709
	Prove (vein study)	410
Non-cardiovascular trials	By-Band	162
	Bluebelle phase A	88
	EVARREST	4

Recruitment figures as of January 2015

Trials in set up

OMACS

TEMPLATE STUDY

IRWAYS$_2$

News

Good Clinical Practice Facilitator

Dr Jessica Harris (Research Fellow) has qualified as a Good Clinical Practice (GCP) facilitator.

GCP training is mandatory for those who are chief investigators/principal investigators of studies or whose principle job role is clinical trial research.

If you are interested in undertaking GCP training, please visit http://www.crncc.nihr.ac.uk for a list of available dates.

New website

Our website was re-launched last November with a brand new look. The website now includes information about our trials, staff and news page.

If you would like to see our new website, please visit **cteu.bris.ac.uk**

Spotlight on: ARCADIA

The study aims to identify special molecules in body tissues and fluids, which could be used to diagnose disease and predict complications in future patients.

ARCADIA recruited their 1st participant in June 2014 within 42 days of submitting its local research and development application. This is well within the national 70 day target set out by the Department of Health.

Patients undergoing heart surgery are asked to donate small samples of bodily tissues and fluids for analysis. The levels of non-coding ribonucleic acids (RNAs) in these samples are then measured to determine whether they are affected by heart disease and diabetes.

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University of BRISTOL

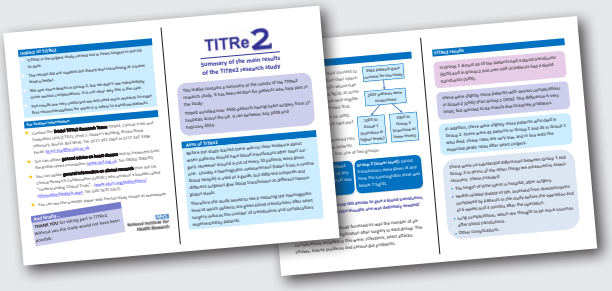
The TITRe2 trial:

A multi-centre randomised controlled trial of Transfusion Indication Threshold Reduction on transfusion rates, morbidity and healthcare resource use following cardiac surgery

Recruitment to the TITRe2 trial was completed in February 2013.

3565 patients were consented across 17 sites around the UK, with 2003 patients randomised into the study - a remarkable achievement that would not have been possible without the hard work of all the sites involved.

- The team at Bristol consented 579 patients with 393 of those randomised!
- The trial protocol, which describes the trial in detail, was recently published in *Transfusion and Apheresis* Science Jun 2014; 50(3): 451–461
- The TITRe2 results were presented at the European Society of Intensive Care Medicine (ESICM) conference in Barcelona (29th September 2014) and at the 28th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Milan (13th October 2014)
- The results of the trial will be published in The New England Journal of Medicine.
- We are preparing a summary of findings and a leaflet will be posted out to participants.



Day in the life of a Statistician

Rachel Nash - Medical Statistician

Working as a statistician in a Clinical Trials Unit, our day-to-day work is very varied and depends on what stage our different trials are at. For example; whether they are in the process of being set up, or recruitment is underway, or the dataset is complete and the final analyses are needed. Our involvement in the trials begins at the very start of a trial, and does not end until all the analysis has been completed and the results disseminated.

At the beginning of a trial, we work out how many patients are needed in the trial, and think about how we will analyse the data. This information is needed when the research team apply for funding. It is important that we include enough patients in the trial to be able to show a difference between the interventions that we are comparing, if there is one. Once the trial has been funded, we then need to work with the rest of the study team to help design the data collection forms. We also work closely with the team who create the database that data are entered in to. This is a really important step, as we can build checks into the database that help us to get really good quality data out at the end.

After the team have started recruiting patients, we are one step closer to carrying out our analysis. Before we can do this, we write a Statistical Analysis Plan describing how we are going to analyse the data. This is done before we see the final data - we do this so that our decisions on how to analyse the data are not affected in any way by the results.

We might also have other reports to produce regularly while the patients are being recruited – these reports are used by the study teams, and other independent oversight committees involved in the trials, to check on trial progress and look out for any safety concerns. They can also be used to keep an eye on other things in the trial as well, such as how well our data collection forms are being completed.

When the trial is finished, we can then analyse the data! This is an exciting time for the study team – we get to see whether the trial has been a success after all the work that has gone into it. We are then heavily involved in writing up the results ready for publication, and preparing presentations for conferences where the results can be shared.

As you can see, statisticians are involved at various stages within our trials. By working closely with the rest of the study team, collectively we are able to produce high quality research to benefit future patients.